UNITED STATES OF AMERICA

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DEPARTMENT OF DEFENSE

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ARMED FORCES EPIDEMIOLOGICAL BOARD

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PUBLIC MEETING

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Tuesday,
September 14, 1999

The meeting was held in the Sanford Auditorium at the Uniformed Services University of Health Sciences, Bethesda, Maryland, at 8:00 a.m., Dr. Dennis Perrotta, AFEB President, presiding.

PRESENT:

DENNIS M. PERROTTA, Ph.D.	President
HENRY A. ANDERSON, M.D.	Member
DAVID ATKINS, M.D.	Member
SUSAN P. BAKER, M.P.H.	Member
L. JULIAN HAYWOOD, M.D.	Member
FRANCOIS M. LAFORCE, M.D.	Member
STANLEY I. MUSIC, M.D.	Member
GREGORY A. POLAND, M.D.	Member
ARTHUR L. REINGOLD, M.D.	Member
CAROL W. RUNYAN, Ph.D.	Member
ROSEMARY K. SOKAS, M.D.	Member
NEIL D. WEINSTEIN, Ph.D.	Member
COL. BENEDICT M. DINIEGA USA	Executive Secretary

ALSO PRESENT:

VAOM RICHARD NELSON, USN
JAMES A. ZIMBLE, M.D.
MARGARET THOMPSON
CAPT. DAVID TRUMP, USN
COL. DANA BRADSHAW, USAF
LTC(P) DAN WITHERS, USA
CAPT(S) KEN SCHOR, USMC
CDR MARK TEDESCO, USCG
COL. WARDE, MRCUS
LCOL FRANK SOUTER, CFMS

A-G-E-N-D-A

P-R-O-C-E-E-D-I-N-G-S

(8:10 A.M.)

DR. PERROTTA: Well, in this my last meeting as Board Chair, I am wondering whether or not Ben wanted me out a little earlier because we didn't bring the gavel. We will do this. That is my commitment to this Board. I would like to bring the fall meeting of the Armed Forces Epidemiological Board to order. I would like to welcome everybody. This is an odd feeling, so I am going to say welcome to everyone. I will do this eye contact thing and then move on from here.

I appreciate everybody taking time out of their busy schedules. We have, as usual, a very busy agenda. I'd like to start out with welcoming our honored guests, Dr. Zimble, the President of USUHS will be here shortly. To my right is Vice Admiral Dick Nelson, who is the U.S. Navy Surgeon General. Admiral, thank you for coming. I understand that Admiral Nelson will be able to spend a few hours with us this morning, and we appreciate you taking time. If there is anything the Board can do to help you with your time here, please let us know.

To my left removed once is Mrs. Margaret

Thompson, who is -- I am probably going to call her our handler for the AFEB. She is in charge of the 14 -- how many -- 15 different committees that the Army has. she is on the Army Committee Management Office. So part of the work that she does is help us get through the paperwork and give us some guidance as a Board, the Army handling us.

I understand that President Zimble is here. Good morning.

DR. ZIMBLE: Good morning.

DR. PERROTTA: I am Dennis Perrotta. Thank you very much for making it.

DR. ZIMBLE: My pleasure.

DR. PERROTTA: And thanks for hosting us here. Let me also express our thanks to our good friend, Colonel Gary Gackstetter, who has been trying to escape up there. Gary has been a friend of the Board and an avid participant for many years. In his not so new role here, we appreciate your coordinating our Board. Also, a bit of a note for Major Carol Fisher, who is over there. Everybody on the Board knows Carol as a person who has been helpful in getting us organized, which is like herding cats. The good news is that she is here and again is

helping us. The bad news for us and for the Board is that Carol will be moving to Japan on Thursday, the day after this meeting, for her new permanent station there. There is a farewell luncheon for Major Fisher on Wednesday at 12:30 at the Benihana Japanese Steakhouse, an appropriate setting. That is at 7215 Wisconsin. And if you would see us about RSVP, we can give you instructions or details on that.

As you might expect, a meeting of this size and all the work that gets done in making sure that things run smoothly in spite of the work that I do, we have Petty Officer Mitchell, who I think I just saw. There he is, over there. He is our go-to man, and we appreciate your work here, sir. If anybody has any issues or problems logistically, let's get with Petty Officer Mitchell on that.

Finally, as you all know, Jean Ward is working behind the scenes. She is at the office, and we would like to thank her for her administrative support and getting me my tickets to get here, which was quite a feat in itself.

Colonel Diniega, do you want to continue with some more of the announcements?

COLONEL DINIEGA: Yes. Just a reminder

to everyone. The meeting is being recorded and transcribed. The transcriber is on the right. So we have microphones on the table. Try to use the microphone and make sure you speak into them, because he is recording off the audio system.

Members of the press are present in the audience for various parts of the meeting. The snacks, breaks and lunch are in two locations. We don't have anything available here in this room, but in the bottom lobby to the left is the cafeteria with various types of snacks and foods available cafeteria style. You don't wait in line. You just go to wherever you need to go to get your things and then you wait in line to go through a cashier. There is a Navy Enlisted test that is being conducted from 8:00 to 10:00. So during those periods, you can go in and buy stuff, but you have to leave the cafeteria and eat it elsewhere. There is also William III, which is a coffee shop/pastry shop/sandwich shop deli style that is in Building C, which is catycorner this way on the first floor. There are very few tables to eat on, but they have the big amphitheater-like structure between the buildings that you can sit on to have your snacks or your lunch. I am not too sure if they

are allowed coffee in here. Let's don't spill it. That is why I don't have coffee.

DR. PERROTTA: I feel a new subcommittee being formed, the clean-up subcommittee, Henry.

DR. ANDERSON: I didn't see any signs. There were no signs.

COLONEL DINIEGA: The sign-in rosters are out in front at the registration desk. Just make sure everyone signs in, so we know who attended the meeting. I have some phone numbers for messages. The first number is at the Department of Preventive Medicine and Biometrics. That is 301-295-3170. There is a phone here in the auditorium which will ring, so it might disrupt what is going on. But that number is 301-295-1959. Telephones for DSN use -- there is another phone up in the top behind the projector room and several phones in the lobby near the elevators and across the lobby on the wall. Bathrooms -- women's are outside in the lobby to the left and men's are on the other side of the lobby to the left.

On the agenda, if you take a look at today's agenda, the agenda is full. So I request that the speakers -- I remind the speakers to try to

stay on time and also please make sure that I have or Major Fisher has a copy of your presentation so we can include it with the transcribed minutes. Carol, did I forget anything?

I, again, would like to thank Colonel Gackstetter and USUHS for all their support for the meeting and really acknowledge also Major Fisher, who through the past year, although not assigned to the AFEBMO any more and assigned to GEIS, has volunteered graciously to help during the meetings. So she has helped with every meeting during the past year that I have been the Executive Secretary. Thanks again, Carol. And thanks to Petty Officer Mitchell, who was assigned to us yesterday and is doing a great job of helping with the meeting.

DR. PERROTTA: Dr. Zimble, would you like to welcome?

DR. ZIMBLE: Yes. Good morning and welcome to the Uniformed Services University of Health Sciences. I, first of all, Dr. Perrotta, want to thank you for selecting the University as a site for this meeting. This appears to be a little bit awkward. We do have some space limitations, which may be solved by building E, which we hope will soon

be in the MILCON queue. But at any rate, any way that we can accommodate you. We would certainly like you to return. I first learned of AFEB in 1981, when I became a flag officer and I was a medical officer in the Marine Corps and attended some meetings at the old WRAIR. That room is much more accommodating, but it is condemned basically. It is condemned on the basis of age. This University at one point in time was essentially condemned, not by age, but more by short-sighted budgeteers, who are rewarded for saving outlay dollars and didn't understand the purpose and the scope of this University.

We are beyond that now. So we are going to be here for a while. Again, I am honored that this body should be here. I want this University to continue to maintain its stature and to grow as the academic center of the military health system. If we are to be an academic center, then certainly the academicians of the AFEB ought to feel that this is their home as well.

Now all of you are American citizens. All of you are taxpayers. This is your federal university, and we are run on appropriated funds by Congress. So by all means, it is your University and

I welcome you and ask that you consider opportunities to return. And if we can accommodate you with some better arrangements, we will certainly work with you to try to do that.

I was asked to talk a little bit about the history of the University. I don't want to take up too much of your time. You've got a very tight agenda. So let me just give you a fast thumbnail sketch.

In 1972, a very unpopular war finally ended. Along with that, we lost conscription as a way of doing business. That was coincident with the Vietnamese War. Well, we had a terrific loss of military physicians that occurred with that. We had no good acquisition plan for continuing to maintain military physicians without conscription. We went through, I think, the nadir of military medicine during the 1970's. It was a time when we could not recruit to fill all of the requirements. Some of the physicians recruited were of less quality -- certainly couldn't speak the language well in many cases. And we had some significant quality incidences that occurred within the military that made it a really demoralized activity.

Around the same time, Congress recognized that there were some problems in maintaining adequate physician strength within the military services, and they came up with a statute which did two things. It created this University as a "West Point". As a Navy man, I took some umbrage with that -- but as the "West Point" of military medicine. And the HPSP program, the scholarship program, which was basically to be analogous to an ROTC for the military. 90 or 85 percent of all the acquisitions were to come through the HPSP program, and about 10 percent of the acquisitions were to come through this University.

That all seemed fine. The Department of Defense spends a lot more money on this University per student than it does on the HPSP students. And anyone here who has children recognizes it is cheaper to pay for their tuition than it is to buy a university for them. So that is true. But if you look at the total amount of money the taxpayers spent at other universities as well as this one, the cost to government, the federal cost, per capita for students here is no different than it is anywhere else.

Secondly, we found that we met and

exceeded the expectations of those legislators who put this University into being. We did that because we enhanced the career motivation of our physicians. The first year was 1976 that the first students came on board. The first graduating class was 1980. In 1980, we graduated 29 physicians. It is interesting that about 80 percent of them are still on active duty. We have gradually increased the size of the classes, so that now we graduate about 165 students a year. We have graduated close to 3,000 altogether since the school opened. 92 percent of them are still on active duty today, many of them indentured with a 7-year obligation that follows their graduate medical education. But nonetheless, they have made a decision to be career military. They now represent close to 20 percent of all the active duty military.

Now we think we do more than just recruit -- act as a recruiting office for these physicians. We give them a basic foundation in not only how to practice medicine in the military, but how to practice military medicine. They get about 700 extra contact hours over other medical schools in terms of giving them that military flavor. They know the military uniqueness of the practice of medicine. And

I don't just mean combat casualty care or logistics. I think primarily the major focus is epidemiology. The major focus is preventive medicine. The major focus of this University, above and beyond any other medical school in this country, is truly to teach people of worldwide environments, of worldwide climatic conditions, worldwide epidemiology, and how to keep troops from becoming patients, not just treating them as they are patients.

So we really instill preventive medicine and epidemiology into our curriculum at various steps along the way. That is why really I am basically so pleased that the AFEB has chosen this location for one of its meetings.

In addition to training a military physician who is career oriented, we also have a graduate school of nursing and advanced practiced nursing. We also are involved very much in continuing education and we want to invest in the continuum of medical education, especially with the uniqueness of the military flavor throughout the total career of all of the healthcare providers. So we have a very strong investment in continuing health education, a strong investment in graduate education

of the basic biomedical sciences necessary for us to maintain our 7-year LCM accreditation. And we are very proud of the products that we are getting from the research that we are providing, much of it military related but not all.

At any rate, that is just the fast thumbnail sketch. We have been under the gun for about every year since I have been here until this one. I have been here now 9 years, and 8 of them have been dedicated to defending this University. This year, for the first year, we have gotten full budget and we expect to get a full budget in 2000 as well. So I can stop defending and I can start nurturing and growing the University.

We are doing a great deal internationally, and we want to do a great deal more. But we feel that we have earned a significant presence in academia, and we are going to maintain it.

So with that brief thumbnail sketch, I will let you get on with your agenda. Again, I thank you so much for coming, and if you don't mind, I might like to just bounce in and out of here periodically during the day. I have insisted that I

stay on the mailing list to come to meetings. I have unfortunately never been able to attend the meetings. That is why at least if it is here, I ought to get to it. But it is not working out that way either. I have got to run and now welcome some people from the Indian Health Service. I thank you so much for coming and have a great meeting.

DR. PERROTTA: Okay. One of the more important parts, at least as Board member, is to hear what is going on with our preventive medicine officers. So let's start with those reports. Captain Trump is in Health Affairs.

CAPTAIN TRUMP: Good morning, Dr. Perrotta, Board members and Admiral Nelson. It is my pleasure to kick off the preventive medicine officer reports this morning, and my challenge is either to keep us on schedule or be the scapegoat for getting us behind schedule here with the first presentation.

I am going to talk about just some of the things that obviously Health Affairs is involved with -- the ones that I have responsibility for in particular.

One of the things this Board has been very helpful for is giving us recommendations on a

variety of issues. Several that have been made recently have been focused on immunizations. We have moved forward with making those into Department of Defense policy that then can become Service policy and practice to sort of set the tone for what we do down through the organization.

One of those is on the use of inactivated polio virus vaccine, based in part on the recommendation of the Armed Forces Epidemiological Board and then also on the recommendation which came out from the Advisory Committee on Immunization Practices in June to really make the transition from oral polio vaccine to the injectable inactivated polio virus vaccine, especially for children. But getting the guidance out there especially for the military recruits and deployers and travelers that the oral vaccine is going to be going away, and we need to start the transition soon to using the inactivated vaccine for that booster dose. We routinely have given recruits or others who are traveling a single dose to protect them against the risk associated with polio during deployment.

What that thing on the right means is that it is in the Military Health System Executive

Committee coordination. It has gone through sort of the initial level of coordination within Health Affairs. It now goes back with the Services, the Surgeon Generals in particular of the three Services, for one final look before Dr. Bailey, the Assistant Secretary of Defense for Health Affairs signs it and makes it a policy.

Lyme disease vaccine -- very much it was the Armed Forces Epidemiological Board recommendation as far as its application for our military members, and really the guidance is to follow the DCIP recommendations in individual case-by-case decisions. The importance of local commands and local hospitals to make their own plans and policies for administering the vaccine that are based on local conditions and local risks and are coordinated between military and civilian public health practitioners in that local area.

The next item on the to-do list is a similar policy statement on varicella vaccine. Another one that we are now in coordination with is reporting adverse events following administration of the anthrax vaccine. You will hear a great deal more about the anthrax vaccine immunization program -- I

think it is this afternoon on your agenda. But one of the things that has been a major effort there is to look at adverse events that are being reported following administration of the vaccine using the form. There is one, the Vaccine Adverse Event Reporting System of FDA and CDC. And realizing we need to put a modification to our guidance out there in the field. We focused on anthrax vaccine, but I think this guidance would apply to other vaccines in the future.

The other bullet there is one of the recommendations that came out of this committee and the Subcommittee on Infectious Diseases was better ways of getting information out about military immunization practices. We have established a military immunization web page, which is on the Tricare Health Affairs site. That is at least one source for access to policies and recommendations that will be used to provide immunization services practiced here in the military. There are a number of links that fit that though to the Public Health service sites, because our programs are based on ACIP and other recommendations from the Public Health Service. One thing I would like to see and it

follows on is an AFEB web page. Colonel Diniega has talked to me about that, and we are in the process of getting that established. I talked to Dr. Poland this morning about getting the vaccines with the military report on-line somewhere so that that can also be available and link through and supporting information for our immunization program.

One of my roles for the Department of Defense is the ex-officio members of the Advisory Committee on Immunization practices representing the Department. Two issues in particular have relevance right now to our military program. One is discussions recently about a meningococcal vaccine for college students. The ACIP is in the process of relooking at different meningococcal vaccine recommendations and making more specific recommendations regarding college students. It doesn't have much of an impact on our military program other than that the military experience with the meningococcal vaccine, giving it to recruits now for almost 20 years, is certainly supporting information for CDC making their recommendations about the potential effectiveness of the vaccine program for college students.

The ACIP has also undertaken or established a working group on vaccination and bioterrorism issues with an initial focus on anthrax vaccine potentially and probably working through to an ACIP recommendation that would discuss the prevention of anthrax in relation to bioterrorism threats both of anthrax vaccine used as prophylaxis if an anthrax exposure has occurred. That certainly is something the Department of Defense could provide input to. Part of the working group would certainly have access to any experts in this area up at the U.S. Army Medical Research Institute for Infectious Disease.

One of the other things that is on the list that as an ex-officio member, I can make recommendations as far as membership in the Advisory Committee for Immunization Practices. They have several openings that they are hoping to fill over the next year. As one of the Board members, I would certainly entertain your recommendations for individuals in your broad sphere of influence and contacts that would be good representatives to that Board. Not necessarily to represent DoD, but to do the work with the ACIP.

Again on the vaccine issues, there have been Congressional hearings, which you may have heard about, regarding safety of vaccines by the House Government Reform and Oversight Committee. Vaccines and finding the balance between public health and personal choice. A great deal of focus during that hearing back in the beginning of August on childhood vaccines, hepatitis B vaccine in particular. But there was a great deal of attention to the Anthrax vaccine program during that period. We expect within the Department to have additional hearings focused specifically on Anthrax vaccine. But certainly continuing concerns about the safety of our vaccines, the risk of vaccines and their benefit, how to communicate effectively what those risks are and what those benefits are to the individuals, whether they be in uniform or whether they be in the civilian sector about what vaccines have done for us as a nation and as a world community over the last several decades.

Again, on the Anthrax vaccine, a great deal of attention in that area. Lieutenant Colonel John Grabenstein, who has recently come on board as a Deputy Directory of the Anthrax Vaccine Immunization

Program, will be talking in more detail about the Anthrax program this afternoon.

The other area that certainly is of ongoing interest is the Force Health Protection Program. Some of the involvement of this Board in that area -- obviously everybody's goal is maintaining the health of the force, much as you have heard from Dr. Zimble earlier today. In a follow-up to the various groups that have looked at illness among the Gulf War Veterans, the most recent oversight group is the Presidential Special Oversight Board that was established in 1998. They are looking at a variety of things, mainly on the investigation of chemical, biologic or environmental agent exposures or incidents in the Gulf. They are also monitoring how we are doing as far as implementing the Presidential Advisory Committee recommendations for improvement in our deployment and health care system, both in DoD and VA.

In their interim report back in August of this year, they had several questions on deployment health assessment. Those are the very short assessments that are administered just before deployment and upon return to try to assess and

document the health status of individuals about the inefficiency in the way things were done during the Gulf War. And in particular, asking questions about why we excluded routine shipboard operations from some of those requirements and why only deployments of greater than 30 days had a requirement for the health assessment. And one that has been debated many times and are changed to say that the HIV screening samples, even those who are not 100 percent for a particular deployment are sufficient to be in our serum repository for deployment vaccines. I think we had a chance after the report came out -- my boss, General Claypool and Admiral Mayo, who is the Deputy Director for Medical Readiness of the Joint Staff presented to the Board answers to different questions. I think we answered many of those, but there are some issues that they brought up in particular with how effective these policies are with regard to Reserves and National Guard members. Is the requirement such that they would be covered by deployment health assessments.

We also looked at the medical recordkeeping during recent deployments. The Department, based on visits by Dr. Bailey and others,

have identified some concerns with how well we were doing with meeting requirements for documenting in the medical record events that happened during deployments and making sure that those pieces of paper that were generated in the field got back into the permanent medical record. There will be ongoing efforts to make sure that those policies are in place out in the field.

The last several slides I will look at will just be about the hepatitis C virus. I think we are all aware of the increased concern about hepatitis C virus infection in the population and its prevalence. In some of the early reports that came out in the Veterans Affairs patient population suggested that those VA patients had an extremely high risk of hepatitis C infection. That generated attention from the Senate Armed Services Committee, and in the report back in the fall of 1998, they directed us to study the extent of hepatitis C infection in our military population and look at the advisability and feasibility of doing hepatitis C virus testing, in particular during separation and retirement physicals, but also asked us to look at other issues in all recruits or even the total force

for hepatitis C infection.

That generated an effort that resulted in the DoD report to Congress on the hepatitis C virus infection that was a preliminary report based on 10,000 samples that were collected randomly out of the DoD serum repository, those HCV -- those HIV samples that were there. The report was published in April of this year and it was sent to Congress. This is something we are relatively proud of in the team effort between Health Affairs, the U.S. Army Center for Health Promotion and Preventive Medicine, and in particular the Army Medical Surveillance activity and the Naval Medical Research Center, Captain Craig Hyams, in putting together pretty quickly a sero-epidemiological study to provide some objective assessment of what the risks were and base our policies upon that. The Health Affairs policy memo was signed out in June that helped develop screening and a treatment policy for hepatitis C.

What was reported in April was a study of 10,000 serum samples. Over 20,000 have actually been evaluated and the final report to that is being prepared at this time and will be submitted for publication. But what it found was in our active

duty population, we had a 5 per 1000 prevalence of hepatitis C infection. The lowest risk group was actually the active duty who were less than 35 years of age, less than 1 per 1000. The highest risk, 1.7 percent, was among those over 35 and some subgroups. Men and women had similar rates. And that for recruits who were enlisting in 1997, only 1 per 1,000 were HCV positive, and this was based on confirmatory testing in addition to initial antibody testing. After doing some adjustments for age, the risk factors were similar for reservists and active duty. One of the concerns, and tied in particular to what was found among the veterans population, was service during the Vietnam War being a particular risk factor. At least in those who have remained on active duty since Vietnam, the prevalence was actually lower, 1 percent, compared to a similar age group who had not served during the Vietnam era.

What I included in your handout was a copy of the policy and the executive summary from the report. The decision was made that because of the higher risk in those over 35 that screening should be offered for those 35 or older who are separating or retiring from the military service, providing them

with information on the risk factors for hepatitis C, offering them screening if they can identify that they have risk factors, not requiring them to have those risk factors or even to justify or identify those risk factors to request screening, and that that will at least be documented at the time they leave military service and can provide a baseline for follow-up care in the DoD or VA health care systems.

I think most of us should be familiar with this, the risk factors. But if you can answer yes, you may be at risk. And very specifically in the policy saying that you don't have to identify risk factor to get the testing. You may request it if there is no specific risk and documenting that they can either accept or decline testing. This certainly, from our perspective, with the use of some data identified a population that may benefit from a screening program without basing the policy on a sort of limited data that could have been very costly to the Department, whether it was recruiting session screening or other total force or subpopulation screenings. We do not bring this issue to the Board. I think sometimes we give you the tougher challenges, the ones where we don't have the data and

the decision is a little less easy to make. The services are out there now in the process of getting this implemented. You may hear from them how much of a challenge that is.

That is all I have for my part of the presentation. Are there any questions?

DR. PERROTTA: Any questions for Captain Trump? I think we have a good name in nomination for scapegoats.

CAPTAIN TRUMP: Sorry.

DR. PERROTTA: It helps us understand a little bit more about what goes on at other levels. Colonel Bradshaw, Dana, is out of the Air Force Surgeon General's Office.

COLONEL BRADSHAW: For those of you that were able to go to the Army's Force Self-Protection Conference, basically what I am going to do here is trying to reprise very quickly in a condensed version for the AFEB some of the things that I was privileged to present there on force self-protection in the Air Force. And a lot of this is going to be sort of a teaser for some of the things that you are going to get later in the day in more detail. So I am not going to dwell on it very long. I may have more

slides actually than Captain Trump, but I am going to try to finish sooner than he did. So we will see how we do going through.

CAPTAIN TRUMP: I love competition.

COLONEL BRADSHAW: All right. Just a quick overview of things here. One thing is I wanted to quickly present the way that the Air Force looks at force self-protection and that is through the human weapons system. I just wanted to introduce that concept to you. Secondly, I just want to quickly go over some issues and challenges that we have, highlighting a few. Some of these may be Air Force-specific, but most of them are really common to issues that we have in all three Services. And lastly, I just want to focus on one issue that has come up with us recently that we may want to present more detail at a later time. I just kind of wanted to throw it out in front of the AFEB as something to kind of keep in the back of your mind.

Just quickly, these are some of the issues that we are dealing with in the Air Force. We have a smaller, more technical force that is having to deploy much more often. We have a very high operational tempo, or what we call ops tempo. We have

had to actually redesign the way we do things in the Air Force. We are going to what is called an Air Expeditionary Force or an Expeditionary Air Force to try and deal with this frequent deployment issue that we have got recently.

The medical side has had to conform to that side and that has kind of created problems in making an optimal force protection, particularly our performance detriments. They can threaten both safety and survival. So those are issues we are dealing with.

Now some of this is from Craig Postlewaite. But basically we use a life cycle approach that is common to all the services in looking at it. But we want to maximize these mental, physical, spiritual and technical capabilities. We look at that in terms of the human weapons system, trying to get performance for sustained periods and hostile environments. It minimizes risks in our mission accomplishment, and obviously that is the thing we are very interested in. We want to harden against the DNBI incidents. One of the things that is of note in the recent Kosovo conflict was that we had zero battle casualties -- zero. So everything we

are dealing with is not due to battle casualty, it was other things. So we certainly want to harden against this, because that can affect our mission.

And then resiliency is an idea we have kind of borrowed from the people on our mental health side and the family advocacy type folks. We want people to be more resilient. We want them to be more durable.

This is what we call the human weapons system. In this case, it is on our line side. They have the weapons system. They have an engine that they have to maintain. Periodically, every few hundred hours, they want to go in and they want to do a maintenance check on this. That is not too much different than what we feel like we have to do with the human weapons system. There are things we have to check on the human weapons system. And we need to follow up with those things.

Now, this airplane up here on the side is an A-10, and it has a titanium kind of reinforced body that kind of protects the pilot. I am not sure I can use this, but you can see it over there. But we also have a human being out here on the side that needs protection. So there is hearing protection.

We need a safety vest so that they don't get run over on the flight line. They need Anthrax immunizations and fitness training and climatization and other issues in terms of protecting our human weapons system.

So there are several things that we are looking at in terms of that. Some of these you may have heard before, but we have got an expanded fitness program we are dealing with right now. The health evaluation assessment review program. There is a lot of issues in management and collection of that. We are wanting to update and revise that, but it is an important tool for our assessing our forces. You heard the issues about deployment health assessment and so on. This is an important tool really for bracketing our people and what their self-reported health status is. Issues on alcohol and tobacco use, which are big money and big morbidity items of course. Injury, which you are going to hear things about this later today from Bridgette Carr and others. And then Anthrax issues you will also hear about.

Just a quick look at what active duty Air Force causes of death were. You will notice that

accidents and suicide are the biggest piece here. Disease is not so big and other things. So that is really what we are dealing with in a young, otherwise healthy population. We have had success in our suicide product team, and there has been a decrease in suicides. But we see that there are some problems in that if you look at the red line here, that red line shows that we have a problem with our older enlisted population. In fact, it seems to be a problem even more with our medical community in terms of suicide. So we have areas to focus on that we need to focus on.

You will see more of this later on when you get the worldwide survey information, but I wanted to highlight this particular slide in that it shows an adverse trend in 1998 here in that all services actually have had an increase in cigar and pipe use and other types of tobacco other than cigarettes. That is an adverse trend. It is going in the wrong direction. So we have got things we can focus on there.

Just to reemphasize the injury issue. On the wellness side you will get this in more detail.

We are looking at a lot of prevention

initiatives. The Prevention, Safety and Health Promotion Council, which is chaired by the Air Force Surgeon General Joe Rudman, but participated in by all three Services, are focusing on alcohol and tobacco use reduction and unintentional injuries. But there are also other groups that are now chartered. The Joint Preventive Medicine Policy Group is chartered under there. We have a working group on sexually transmitted diseases and one on put prevention in practice, the HEAR, which is now chartered under there. So this is an all-encompassing council that goes up to the Secretariat level that is focused on a lot of prevention issues.

This is just the Air Force view of the population health. We are kind of trying to shift in actually all three Services from acute episodic care to this more resilient community population-based sort of health care. That is something that is going on in all three Services.

Just some quick things. You have seen these before, but this is just how we are setting up on the Air Force, a population health support office. There is now a move to do this at the military health system level.

This is your brain on Anthrax. On Anthrax, you are going to hear more of this today. But there have been a lot of issues, especially for us in the Air Force. The Vanity Fair article came out about the time that some of our people at Dover Air Force Base got in touch with some of the people that were mentioned in that article and the Internet on Anthrax. We know things get around a lot. We had a Navy ship that the entire ship got spammed with some e-mail with adverse information on Anthrax. Basically we have got general renewed skepticism on vaccines. hepatitis B vaccine has been under fire and the other vaccines such as the problems that have come out with the rotovirus vaccine. So we are dealing with this all across the scope.

Now, just quickly some Air Force TB screening issues. One of the things that has been required at deployment surveillances from the Joint Chiefs is that a PPD is given within two years of deployment. The assumption there is that we deploy to areas that are endemic with TB and so there is a risk. Now the Vietnam experience would bear that out. The whites had a 3.4 percent conversion rate, and actually there was an increased risk for blacks

there. They had a 17 percent conversion rate for an odds ratio of about 5.9. There have, however, been no studies of Air Force deployment risk since then. The Navy, I think, has done studies with Craig Hyams again, that looked at some of the experience on the Navy side, but we really don't have a good description of what actually is our deployment risk. Our overall population risk we know is very low. It is similar to what is in the U.S. Our population really is not at much risk for TB. The CDC actually discourages low-risk screening for all.

Currently, we screen every two years in our periodic health assessment. The reason for that being we just logistically want to catch everybody before that two-year deployment time. And a very large proportion of our people do deploy within the two-year time frame. Now the Navy screens annually for most shipboard, for instance, and the Marines, because they have very enclosed environments. I think at an earlier meeting we had a presentation of the problems they had with that. But the Army, as I understand, still screens every five years at their periodic physical.

The issue here for us is the false

positive rate. With a 15 mm cutoff on the PPD test, there is about a .3 percent false positive rate. So with our population of about 360,000, that is about 1,000 false positives if we screen everybody. So that is something to deal with. In cost effective analysis looking at school children populations, they would have to have about 20 percent reactives for a screen-all policy.

This is just a quick look at how we are with the TB conversion rates. You will notice that there is sort of some things to notice here. Seven states along the borders, where you might expect more Hispanic immigrants or East Coast, there is a little bit of an increase in reaction or conversion rates. The Far East, Japan, Korea and Guam and also to a lesser extent Hickham in Hawaii, they have a little bit higher rates. Places like Hurlburt Field here in Florida, that is our special operations squad. So there are some people who are going out in rural areas overseas and are going to be in with the local populations and they have an increased rate. But other places, northern tier states, are really pretty good and more like the U.S. population as a whole.

So there is a lot here -- and of course

Europe has very low rates, except Izmir in Turkey, and to a lesser extent Incirlik in Turkey. So there are some things we need to look at in terms of our population. And these are some things we have proposed to do in the study. We want to look at geographic factors. We want to look at what actually is the deployment risk and is that based on where you deploy, how long you have been there. That may address that 30-day rule that we were talking about. What is the risk of deployment and how does time figure in as a factor? Is there an occupational risk? The Vietnam study did not show there was an occupational risk, but health care workers we know have a risk. Are there other occupational workers? We know, for instance, that at Hurlburt field, we expect our special ops people will have a higher risk because of where they go. Contact and family factors of course we know and then race is an issue. And we want to look at this in a decision analysis and cost analysis.

So that is sort of where we are going and what we are in the middle of. I will end with that. I know there is -- I will entertain questions because I know there are other people that need to speak.

DR. PERROTTA: Dr. Sokas?

DR. SOKAS: Yes. I just wanted to add if the Vietnam study and the current conversion rates are based on entry two-step PPD's as opposed to you just have the one and then a year later somebody --

COLONEL BRADSHAW: Right. The Vietnam study actually used TB tine. It wasn't even using PPD testing. So that is a little hard to compare. We at the University here when I was here in the Department here at the University in the health clinic for the medical students, we did do two-step entry testing. But to my knowledge, I don't think any of the others

-- any of the Services do that for all personnel.

DR. SOKAS: Okay. Because obviously that makes the early years after entry into the Service of conversion rate suspect that you might just be picking up baseline.

COLONEL BRADSHAW: Right. We do that here at the University, but I am not aware of doing it elsewhere.

DR. PERROTTA: Other questions?

COLONEL DINIEGA: I just have a comment. We were going to put TB in the military on the

agenda for this meeting because there are issues with screening also and some new tests coming out. But we were unable to have the speaker put that together in time. But it will be on the next agenda.

COLONEL BRADSHAW: Yes. There is a study that has been done in Africa in Kenya on Quantaferon on that test. So that is one of the things we will be thinking about in our decision analysis.

DR. PERROTTA: Thank you, Dana. Lieutenant Colonel Withers. Ben is the PM officer out at the U.S. Army Surgeon General's Office.

LIEUTENANT COLONEL WITHERS: Thank you, Dr. Perrotta. I have no slides this morning. Let me introduce myself. I am the new Army representative to the Board. I am Lieutenant Colonel Ben Withers. As Dr. Perrotta said, I am the preventive medicine staff officer of the Army Surgeon General's Office. I follow Colonel Jerry Karwacki, who has departed and is going toward Akron. I want to talk about a few things this morning. One is the reorganization of Army preventive medicine, and the other is Army actions concerning recent AFEB recommendations.

I can characterize the reorganization of Army Preventive Medicine as a movement of our center

of mass from staffs to what is called CHPPM, which is a major subordinate command of the medical community. CHPPM stands for Center for Health Promotion and Preventive Medicine. This movement began really in the early 1990's, when the former environmental hygiene agency was renamed to the CHPPM and several preventive medicine personnel and monetary assets were transferred, mainly from the Office of the Surgeon General to the CHPPM at that time.

It continues now beginning in FY2000 with the transfer of MEDCOM as opposed to OTSG, the San Antonio former Health Services Command with the transfer of MEDCOM assets to the CHPPM. Secondly and more importantly, in addition to personnel and perhaps money flow, there is a change in responsibility. CHPPM will pick up responsibility for planning policy development and in fact policy making.

This could easily be an evolutionary step toward -- the end-stage of this evolution would be a preventive medicine command which has total authority and resources for all Army preventive medicine, all the way from planning and policy making down through execution at the post level. In the current status

of the evolution, CHPPM will still not own the executionary assets at the local level.

Moving on to the Army actions, I just want to go through the four recommendations that the AFEB recently released. Concerning Lyme Disease, this is a fairly easy one in that we had planned to release a policy but with the Health Affairs policy, which in fact mirrors our own, we will await that and most likely endorse in the present state. Our northeast region, Colonel Engler, has developed very robust guidelines for the practitioners to use and we will endorse those on as well.

Concerning chlamydia screening, this has been given to Colonel Darrel Jarrel to implement this. He is forming a working group and will move out on that shortly.

Varicella, I have to say, is uncertain. We do have a problem with resourcing laboratory support if we want to do a quick screening or a quick turnaround of that testing for recruits. That is a problem. You have heard the CHHPM presentation and the model that was presented at your last meeting, which recommended against, but may not have taken all factors into account. In other words, it was limited

in its scope. We have ongoing a pilot study at Fort Knox being run by a preventive medicine officer there which is mitigating for screening. It is about three-quarters of the way through, and I think it will give us some good results that we can use in our planning. But honestly that is about all I can say right now.

And finally, the OPV/IPV. There is really total agreement on this. It is easy to implement and in fact will be dictated by market forces ultimately. Are there any questions? Thank you.

DR. PERROTTA: Thank you and welcome. We are glad to have you on board. I am sure we will be talking with you more. Captain Ken Schor is from the Marine Corps, a preventive medicine officer. He replaces Ann Fallon and is representing Commander McBride, who is on the Navy side, who I think is TDY someplace exotic.

CAPTAIN SCHOR: He is somewhere over in Yokusuka, Japan the last time I checked. I will start off with Marine Corps issues. I am going to try to cover two Services and perhaps be quicker than any of my predecessors. So we will see how this goes.

I am in the seat, Ann Fallon's seat, just for the past three weeks. So I can afford to be short at this meeting and perhaps have a little bit more robust presentation and bring Chestie, the bulldog, with me next time. One interesting aspect is the area of combat stress control. This is a directive by Health Affairs, a DoD directive, that has gone to all the services and we are looking at combat stress control. That directive recommends a standard three-stage prevention model, primary, secondary and tertiary. It also recommends combat stress control platoons out in the field. We are looking at this from a Marine Corps standpoint. I can assure you that the Marine Corps stand has had a program that is housed down at Quantico. It is in the Infantry Officers course. There is also the Amphibious Warfare School. And it is a very robust program that combines didactics -- approximately four hours of didactics with even mock scenarios on treating -- these infantry officers treating combat stress casualties and also recommending that they volunteer in the Washington Trauma Center to see what trauma looks like and to see what their reaction is to this. This has been work by a civilian physician

at Bethesda here, Dr. Fleet B. Giovanni. That is on the web. We are looking at expanding that -- expanding it into senior enlisted and expanding it into more aspects of the junior officers especially.

We are building this model hopefully on a force health protection model where the first two pillars of force health protection, the healthy and fit forces and the casualty prevention, comes under the line, the small unit leader, as it should in our model. And where combat stress treatment falls under the organic medical aspects of the units in the Marine Corps -- the Navy medical units in the Marine Corps. So we are -- in fact, last night we had a global video teleconference to that. We are working with our command combatant staffs to work on programs of implementation and maintaining a very small footprint forward, because we don't have the luxury in most cases of sending psychiatrists forward or mental health professionals forward.

For instance, the 2/6th MAU that has just retrograded from disaster operations in Turkey was also the same group that was involved with the Marine Corps assets on the ground in Kosovo. They don't have any mental health professionals. They have

general medical officers. They have independent duty corpsmen and they have combat medics. So we have to work combat stress control in that environment. There is no more room for any additional personnel aboard those ships. When it is a decision between beans, bullets and black oil, you can figure that the Marines will choose the bullet over any other human assets.

We are also beginning to explore issues in women's health. Women in the Marine active duty -- women Marines have the smallest percentage of any of the Services, but there is an ongoing research program down in South Carolina where we accessioned enlisted female Marines and looking at how we work in health promotion for women's health in that area. That is being worked through the University of San Francisco.

And finally, the new Commandant, General Jones, has invited health services -- I happen to be the rep -- to what he calls his War Room. I think that has been a very positive step on his part. That gives us an entre with 40 other contact officers to let him know and the other folks in policy know what our top issues are. So with that, if there are no

questions about the Marine Corps, I will go on to the Navy for Wayne McBride. Yes, sir?

DR. LAFORCE: What is the fraction of women in active duty personnel in the Marines?

CAPTAIN SCHOR: I believe it is around 10 percent, but don't quote me on that. It is quite small. They are not in any of the infantry units. They are in more of the support units at this point.

As we said, Wayne McBride is in Japan at this point. Captain Trump mentioned hepatitis C screening, and that is awaiting Service policy for implementation as I understand it. Wayne is over in Japan helping to install PHCA, the preventive health care application, in I believe Yokusuka and some of the other hospitals and fixed facilities over there. That is a wonderful application that I was becoming familiar with yesterday that looks at the preventive services task force and provides recommendations no the desktop and is linked to CHCS.

Those are the only two things he asked me to present. Thank you.

DR. PERROTTA: Any questions?

DR. RUNYAN: Just a comment. Two of you so far have raised the issue of mental health issues,

and it seems that that is something that at least in my time on the Board hasn't been addressed, and I don't know if we have necessarily the expertise present in this group to address it. But it seems like something that we might want to give more thought to and perhaps pull in additional expertise to assist with because it is clearly a major issue.

DR. PERROTTA: I think that is a good recommendation. I saw Colonel Diniega write it down. So that is a good idea. Thank you.

COLONEL DINIEGA: I have a comment. There is a briefing on PHCA, the preventive health care application, tomorrow morning by Lieutenant Colonel Fonseca.

DR. PERROTTA: Joining us from the Coast Guard is Commander Mark Tedesco, the medical officer out at HQ.

COMMANDER TEDESCO: Yes, good morning. I am Mark Tedesco. If you really pay close attention to my slides, you will notice that my title, currently chief of medical readiness branches, changed three or four times in the last two years, but my responsibilities haven't changed. Hopefully this one will stick at least through the next meeting

and I can move this slide along.

The two things I want to talk about today are the ARD or now febrile respiratory illnesses being called surveillance programs, which was recently started at the Coast Guard, and also the AVIP, Anthrax Vaccine Immunization Program.

Our ARD program, after a couple false starts, did pick up just about two months ago, and we wish to thank GEIS and the Navy node in San Diego, and the folks in the Air Force for assisting us over the last year or so in getting this program off the ground. We have been gathering specimens for about two weeks -- I am sorry, two months, and playing with some numbers and some lines, we were able to -- the very low incidence rate across those two months create a very impressive looking graph. But basically the total number of folks in any particular week at Cape May, which is our training center for recruits, we had three cases of ARD. So although that looks really impressive, it really doesn't show much. But we hope that by a year from now we can have some good information out of this program.

The thing I will spend a little bit more time on is our AVIP program and one of the concerns

that has come up in the last week or two and hopefully get some input from some members of the folks here today. We currently have 500 in the program. Since it is only given currently in Phase I to folks who deploy, we have had two cutters and a couple of port security units that have deployed to the high risk areas. However, in Phase II, which is anyone who could potentially deploy to the high risk areas, that is going to be about half of our total force of 40,000, are potentially deployable at any one time if called upon. The other thing we are doing, and we will get to this a little bit, is working with the central AVIP staff in the various Service's points of contact on the clinical guidelines, which may soon be published.

We had the opportunity in the last couple of months to inoculate some senior leadership in the Coast Guard at headquarters and also some of the medical personnel involved with the program. We did really passive surveillance on these folks at the time of their second week or four-week shot. We would ask them how it went with the previous shot and get some feedback. But with the medical folks, we were able to conduct active surveillance. It was

very easy to do since we all sit together kind of in a small area. It turns out over 7 doses, we had five local reactions, two of which were classified as moderate, two as severe, and one which was somewhere between moderate and severe, depending on how you actually measured it.

Our observations through this and through our involvement with the program are the local reactions are very calm and somewhat to be expected. Our experience has also shown that they are benign and self-limited. The published data that we have seen we feel has underestimated the number of local reactions to be expected percentage-wise. A lot of the data is from the 1960's and early 1970's, as well as using the product insert. I think we have seen a number of either anecdotal reports, our own experience, and some unpublished reports that show that these numbers, although significantly higher perhaps in terms of recurrence, still are benign and self-limited.

Now we have had the opportunity to review what I was told were stamped final clinical guidelines that are now being put out to the Services for final review. Our concerns are the potential

that these guidelines may be a little bit overly aggressive, particularly in the area of moderate and severe reactions. And our concerns are that our experience in what we have known from either published or unpublished reports and our anecdotal evidence is that these are still relatively benign and self-limited events. But what we are seeing in the guidelines are that if you have a severe reaction, which is anything over 12 cm of erythema or induration, you are -- you must be seen by a physician and you must be started on oral steroids and you will not continue in the program until you have had an evaluation or perhaps and follow-up by an allergist to allow you to continue in this program. We are concerned that this is going to lead to a number of unnecessary exemptions and a diminution in readiness as well as really strained medical and logistic systems that are already strained by implementing this program and trying to carry it forward. And also legal concerns. When these guidelines go out, the feeling that we have at least is this now becomes the standard of care. And if you don't follow that, we may run into some problems. And looking to the guidelines, if someone needs to

see a very busy general medical officer in the middle of nowhere who has got a roomful of troops needing medical care, he may not have time to leaf through these extensive guidelines and see exactly what he should be doing. With something that looks relatively minor and the experience over the last year may be that this is benign and self-limited and that may not carry forth to the extent that the guidelines are requiring.

With that, we would certainly invite -- if there is information we don't have that would suggest that, yes, this is the way we need to be proceeding on these local reactions, especially the moderate and severe ones, we would certainly like to hear that. But at this point, our experience and what we have read does not sort of agree with at least the extent of the guidelines at this point.

Our other concern is it is unclear to us that these were really consensus or evidence-based guidelines. And again, we would welcome input. If we are incorrect in that view, we certainly would welcome that input. And hopefully we will get some input from the other people who are involved in this program or have interest in it over the next day or

two. That is all I have. Thank you. Any questions?

DR. PERROTTA: Any questions for Commander Tedesco? Would you identify yourself for our reporter?

COLONEL ENGLER: Sure. I am Colonel Engler from Walter Reed.

COMMANDER TEDESCO: We did try to call you yesterday, ma'am, also.

COLONEL ENGLER: I am not sure that the Board has seen the draft documents at all.

COMMANDER TEDESCO: No, they have not.

COLONEL ENGLER: So it is kind of unfair in the sense of bringing it up. Your report --

COMMANDER TEDESCO: The only reason I did bring it up is I was told yesterday those were final documents. It wasn't a draft anymore. And that may be untrue also.

COLONEL ENGLER: Right. Well, no, I think you bring up some very important points. In May, when the clinical Anthrax meeting was held at USAMRIID with Tri-Service and Reserve attendance, there was a panel discussion and I gave a presentation about cases that we had seen at Walter Reed or that had been sent to me via e-mail that

clinicians were seeing in the trenches, and the fact that the clinicians were truly scrambling in terms of how to even manage or approach these. And what has happened in too many sites is that the clinical folks, frequently nursing personnel, would tell people this is normal. 102 degree fever is a normal Anthrax reaction, not consistent with the package insert. 12 cm is 120 mm. That is the entire upper arm extending below the elbow. Most of these people do have systemic symptoms. And the rate of women compared to men -- and I brought a copy of the abstract for Gregory Poland that we have submitted -- is twice that for men. So you have a very small and. And how many women were in your group?

COMMANDER TEDESCO: One.

COLONEL ENGLER: Okay. So I think that what you have to understand is that that grew out of a tremendous hue and cry of what do we do with people and a hue and cry from the line from all three Services that made its way to Congress and the Congressional hearings on adverse reaction management, and the DoD was challenged by Congressman Shea to show that they are adequately educating the providers in the trenches how to manage adverse

reaction and that those adverse reactions are being acknowledged and treated appropriately. There is a panel testifying at the Congressional hearings of Service members that was pretty disturbing. If your arm swells starting the evening after the vaccine the way I have described and then you are ill for a week, to be told that that is not due to the Anthrax -- there is no other drug reaction I am aware of where a temporal association like that is not assumed to be due to the drug. And they would get revaccinated and people would get very scared that they were being made sick, fed by the Internet that they might get Gulf War illness and be permanently disabled. All of this testimony on the part of the panel -- the Service members really put a very bad light on all three Services medical delivery system and how it was responding to the problems. So as a result, at the clinical meeting, we attempted to get all the potential descriptions of adverse reactions, not making a judgment about causality but temporal relationship.

I absolutely agree with you and make a recommendation that the draft that we worked on at Walter Reed for dozens of hours with my staff would

then be in a clinical meeting reworked with review by the CDC, et cetera. Because of the pressure -- this is a draft of guidelines. The pressure is to get something out there to begin to work from. The problem of saying I don't have time or medical corps people to take care of the adverse reactions, that doesn't fly very well with Congress. We either can do the job correctly or we can't. And there were several people who testified and sent in to the Congressional panel the fact that it was the Service members calling the GAO office from phone booths because they were afraid to say anything that the message is you will take Anthrax and you will say it is good and fine and nothing is a problem. And if you get sick, you will be "treated as a dirt bag" or as a malingerer or as a bad person. There are several women who have chronic illness and have other diseases that are being identified who were treated very badly which raised the concern of the female Congresswomen as to are we still in an era where women who have problems are just considered complainers or malingerers? The fact that the immune system of women might be different and the response somewhat different to the vaccine really hasn't been

addressed and there certainly isn't any data.

So I would welcome very much that this be reviewed here at the AFEB in detail with some discussion input. Because there isn't any evidence. This is a clinical attempt to begin the process and then by all means make it highly modifiable. It is based on our experience and the experience of a number of other sites that have dealt with -- again, in fairness, relative to the total number of people immunized, we are still talking about less than 10 percent. But I would challenge you that there is no other vaccine where a 5 cm local reaction is considered normal. 12 cm, as I have described, if it happens to you is not a minor reaction. And it is usually associated with a flu-like illness and fever. Ken Hoffman in Korea has collected a lot of data on almost 2,000 people, and it is quite clear that these local reactions are disabling. Now they are due to the fact that there is aluminum hydroxide in this vaccine. In the 1950's and 1960's, aluminum hydroxide -- you can find articles that say don't give aluminum hydroxide containing vaccines subcutaneously, because it will cause serious large local reaction. If you give it IM, it won't be a

problem.

Now here we have a vaccine given by the wrong route, if you will, but that is what is in the package insert. There is preliminary data from USAMRIID that was presented to the FDA in December of 1998 showing that the IM route is equivalent, significantly less morbid, and by the way, the two week dose is unnecessary. Unfortunately, the funding for expanding this study to the numbers that the FDA required to change the package insert was not moved forward expeditiously. And it is a great distress because frankly the guidelines I would rather for large locals, had you all enabled me and my clinical colleagues to give the vaccine IM -- because that would make more sense than pre-treating and topical --

COLONEL BRADSHAW: Let me speak to that. And Colonel Grabenstein may speak to it later. But the longitudinal study committee, which Dr. Poland is a member and others, we are pressing to get the IM study. So that is on the agenda and we are trying to increase the prioritization of the IM route.

COLONEL ENGLER: Right. But again, at this point, before we change to -- that is going to take time and I would like some help. In any other

practice, a physician does things off the label if it medically, immunologically makes sense. Because Anthrax is a political program, in a sense the clinicians hands have to some degree been tied. So that being able to give the IM route already before the whole -- as you know, it takes time to do the studies and get the FDA approval. To those people who have had serious adverse reactions in terms of the local would make sense, particularly those that are motivated to continue or high risk in view of deployment. But there are a whole bunch of clinically challenging questions that as this program expands and as the number of doses increase, where hyper-responder frequency is going to increase -- we learned from rabies and we learned from pneumovac that giving too many doses will eventually make the subpopulation of hyper-responders sick. And we've got to address that before we get past the sixth dose, especially as we get to the million and a half. The issue of the management -- I mean, the Reserves are desperately in need of help. They don't have enough resources to manage the problems, and that is what the Congressional hearings asked. Do you have enough resources to manage this program, and I think

the answer is no. And that what needs to happen is additional resources need to be identified and we need to develop training networks to assist people.

So the guidelines are a first stab based on -- remember, we are on external review. I was attacked that I was being too aggressive in continuing immunizations, and I said I don't feel comfortable doing this by myself. There needs to be an expert group, preferably also from CDC, this group and civilian consultants as to us moving ahead with immunizing. The problem is if somebody gets sick as we ignore some of these things in a more chronic way, we will potentially be open to great criticism. So we've got to make it visible and open, and by all means we need to attack those guidelines, but we need to work them out.

DR. PERROTTA: Are there any other questions for Commander Tedesco? Thanks, Colonel.

COMMANDER TEDESCO: I appreciate your comments.

DR. PERROTTA: Colonel Andrew Warde, who is our British Medical Liaison Officer is up next. And Andrew, you have some guests that you would like to introduce?

COLONEL WARDE: Yes, Dr. Perrotta and everyone else. I would just like to thank the Armed Forces Epidemiological Board for allowing three of my British medical colleagues to attend today's meetings to observe the work of the Board. I would like to introduce them to you. First of all, Colonel John Graham, who is a public health physician and the British liaison officer here in the National Capital area responsible for Gulf health issues and Veterans Affairs. Next to him is Colonel Robert Thornton, who is visiting this week from the Tri-Service Surgeon General's Department in the British Ministry of Defense. He is the Assistant Director of Medical Policy and responsible for the development and promulgation of strategic policy, standards for the promotion of health, and the prevention of disease and coordination. Next to him is Colonel Simon Miller, a consultant in public health medicine. He is from the Army Medical Director with responsibility for health policy and health surveillance, communicable disease control, and commissioning the coordination of health related research. He is also the Parks professor of preventive medicine. This was a post created in 1860, when the Royal Army Medical

College was founded, and he is responsible for teaching Army doctors about aspects of preventive medicine of military importance. The visitors from the UK are spending this week in the National Capital area. Yesterday, we had a very useful visit to the U.S. Army Center for Health Promotion and Preventive Medicine. This morning, as I say, we are very grateful for the chance to observe the work of the AFEB. We are meeting with members of the Department of Preventive Medicine and Biostatistics of this University this afternoon, and visiting the Walter Reed Army Institute of Research tomorrow. We are holding a working group on Thursday morning aimed at making further progress on harmonizing systems for deployment health surveillance between the allies, and then attending the joint preventive medicine policy group meeting in the afternoon. To wind up the week on Friday, we are visiting the Army Surgeon General's headquarters. So a very busy week and a useful one. Again, thank you, sir, for allowing their presence here today. That is all I have to report.

DR. PERROTTA: Any of the Board members and military staff will avail themselves to our

colleagues from the UK and any questions they may have.

COLONEL WARDE: Thank you.

DR. PERROTTA: Lieutenant Colonel Frank Souter from the Canadian Medical Liaison Office.

LIEUTENANT COLONEL SOUTER: I will be very brief to get us back on track here. What I would like to do is just update the presentation I gave in April in San Diego. Some of you who were present for that and my subsequent presentation at the APIV conference would note that there are numbers in our Anthrax adverse effects study that didn't jive. What I have for the Board are the final numbers and the final rates of events.

Essentially to punctuate what has been said in the last couple of presentations. The rates are significant, especially with the mild events, 9.5 percent with the 576 is what we found. Moderate is 0.5 percent. We have had no severe reactions and 5 systemic reactions over this 576, with the possibility of a sixth that is going to Health Canada's Causality Committee to determine whether this actually was an adverse event. If you recall, this was a neurological reaction at 6 months.

So once again, I am going to say to you this is not the final report because it does have to be reviewed by Health Canada. But at the next Board meeting, I will submit a final report. This interim has been given to the Secretary.

The other thing I would just like to alert you to is that the Canadian Forces is currently engaged in a fairly large retrospective environmental hazards assessment in areas of Croatia, where some of our members saw active duty in the 1993 to 1995 time period. I can't report on the findings of that assessment at that time, as it is subject to a Canadian Board inquiry, but I should have some information for you again at the next Board meeting and I will pass it on at that time. That is all I have to say unless there are any questions. Thank you.

DR. PERROTTA: Thank you, Frank. Any questions for Lieutenant Colonel Souter? Okay. I would like to take the chair prerogative and do a little rearranging. What would a meeting of ours be without a little rearranging. We have one of our speakers, who I think is not yet here, in the next session. So what I think I would like to do is ask

Greg Poland to make a presentation of some of the work that his committee has done, and then we will take a break until 10:00.

DR. ATKINS: Debbie Maiese is here if that is who you are talking about.

DR. PERROTTA: No. We have got somebody else.

DR. POLAND: Well, for almost two years I think it has been we have been working on this Vaccines in the Military Report. It has come to gestation and the delivery was easy. It is a healthy baby, I am proud to say. I have taken merciless kidding from my subcommittee about the thickness of this report. However, next to it on my table this morning was this other report, and I just want to point that out to those who engaged in the personal attacks on my -- no, I am kidding. It is not that big. I hope it will be useful.

I particularly, after two years of work -- you know, it always comes down, for those of you who write grants for example, it always comes down to that last week. Well, it came down to this last week, and I particularly want to acknowledge Nicky Jordan. And, Nicky, if you will just stand up for a

minute because I want to give you a round of applause for what you did. It is not to embarrass you but to truly recognize you. Nicky and CHPPM took on the responsibility of publishing and binding this thing. The one thing that I was just most pleased about is that Nicky was on the e-mail to me nearly every day getting the details of this straightened out with about a week's notice getting it printed so that we could have it at the meeting here. We only have one box. The second box, I understand, is coming this morning. So there will be a copy for each of the Board members. Colonel Diniega has been a supporter of this project all the way through. So we are going to give him the first signed copy by Dennis and myself. So thank you all for your input into this.

COLONEL DINIEGA: All the credit goes to the subcommittee and all the other people who helped. And thanks to the CHPPM for volunteering as they did with the injury report that AFEB put out for volunteering to sponsor the printing and publication of the immunization report.

DR. PERROTTA: And as President, I would like to echo those thanks to CHPPM and everybody there, but to really focus my praise on the

subcommittee chair, Greg Poland. In the six years that Greg and I have been here, he has been an absolute go-to guy whenever we needed something. And when Captain Trump would call and say we need something, I would say let's give Greg a call, and he was always there for us. And this report -- while he said the delivery was easy, this is a huge baby and an excellent piece of work. So, again, I would really like for us to recognize Greg's leadership and his writing and herding the cats who were on the committee.

Before we take a break, I wanted to pass along a word of remembrance for a former AFEB member, Dr. Llewellyn Legters, who was the Chair of Preventive Medicine and Biometrics here at USUS who passed away in August. We had a burial and service yesterday. So one of the former members on this Board has just recently passed away. A moment of remembrance for Dr. Letkers. With that, let's go ahead and take a break until 10:00 and we will start with Debbie Maiese.

COLONEL DINIEGA: Hold on. Just a reminder, testing is going on in the cafeteria. You can still go in there and buy stuff. Otherwise, go to

William III, which is catycorner of the courtyard on the first floor.

(Whereupon, at 9:39 a.m. off the record until 10:01 a.m.)

DR. PERROTTA: The only thing constant is change. Are you okay by this, Colonel Diniega?

COLONEL DINIEGA: Yes.

DR. PERROTTA: I appreciate your flexibility. Because of schedules and timing from some of our speakers and for flow of material, let's start this morning's Health Promotion and Maintenance Subcommittee Meeting with a presentation from somebody that would be presenting in the Environmental and Occupational Health Subcommittee. Major -- let's see and make sure that I get it all right here. Major Bridgette Carr is from the Air Force Safety Center and is going to present some information on sports and recreational injuries in the Air Force. We would like to thank Professor Baker for making the recommendation that Bridgette join us. Good morning. After that, we are going to have Debbie Maiese and then Dr. Bob Bray, for those of you who need to know the schedule for the next hour.

MAJOR CARR: Good morning. I am from the

Air Force Safety Center, as John just said, and the research function at the Air Force Safety Center is relatively new. I don't know if anybody here is representing other Services safety center. Typically they are a group that takes care of mishap investigations and reporting. The research function is new and they wanted an epidemiologist there thanks to your recommendation. I have been there two years. I was the first person to perform the research function. Pretty soon we are going to be six strong with two epidemiologists.

I wanted to introduce you to the Safety Center and my purpose is mainly two-fold. To let you know of the resource there, know of the immunological research at the Air Force Safety Center and other Safety Centers, and also open the door to looking for partnerships between the safety and medical communities, because this data base there in the research function is kind of an untapped goldmine, as hopefully you will see by me walking you through a very, very quick study.

The research team right now -- as I say, we are six strong. There are going to be two epidemiologists. Colonel Robinson is coming at the

end of the month. We have two psychologists that were picked by default, not necessarily by design. We have to have two psychologists. One is an IMA and one is a Ph.D. research. And then two data analysts who have been at the Safety Center for a long time doing simple statistics and helping with the flight mishap reports.

Some of the data issues I want to make you aware of. The Air Force instruction that guides the reporting and investigation process is our Air Force Instruction 91204. It is a huge, thick, complicated document, but for the purpose here I want you to be aware of one of the things that will trigger a report for a military member or an Air Force member I should say is that the person misses a day subsequent to their injury -- they miss a day of work subsequent to their injury. So we do not at all catch, for example, out-patient data where they would return right to work. Nor would we catch someone who was injured on Friday and they felt better by Monday. We miss all of those too. We kind of call it the Friday night syndrome or the weekend syndrome. We miss all of those. However, if you live with this bias over time, you can certainly use the picture

over and over again for a comparative, as you will see.

So for active duty, be aware that all of these are captured for on and off-duty injuries. The data base has been computerized since 1987 and prior to that everything is saved on microfiche.

In sports and rec -- as you saw, that was computerized since 1987, so I just used the computerized data base. So this is our active duty Air Force statistics, if you will, and brief epidemiology. The source for injuries is our data base, the Air Force Safety Center, and of course by compared to Randolph for the population proportions.

It has been modified over the years, the definitions, because the AFI has changed a little bit. Right now the sports and injury report is just 15 fields required, where before there were 34 to 50. And just to help organize this, the word I have drilled into is ground mishaps -- in other words, not flight and not weapons. The subcategory is sports and recreation, so they were off-duty only people, and they are sports and recreation. Not domestic, for example, people hurting themselves in the kitchen or working on their cars. This is true sports and

recreation. And also just for information, we are going to publish a -- not unlike the injuries in the military, the hidden epidemic book -- we are also going to publish one from this data base on injuries in the Air Force, a technical report.

If you look at the reported sports, these are how they are proportionately. Basketball and so on down the line. This is not to say by any means that basketball is more dangerous. It is mostly a reflection that it is the most popular. And as you can see, the top 3 make almost half of all the sports and recreation injuries. Again, it doesn't mean they are the most dangerous per man-hour of play. It is likely that they are the most popular. If you look in the sports medicine literature, you know football per man-hour of play is one of the more dangerous sports, but not necessarily basketball.

If we look at what were the most costly in terms of lives lost in severe injury, these are the sports and recreation activities. Losing people in the water and injuring people in the water and so on.

I will just do a very, very quick overview, and again all of this will be in the

technical report. If we look at the age distribution of our population over the last 10 years, this is an average. So this is our age distribution over the last 10 years of our total force, men and women. You see where over the last 10 years, we had been about 16 percent women in green. If we look at just the injured, the distribution is relatively similar. So you can't say that we are overrepresented in certain ages nor sex.

We realize that our military has been declining or shrinking over the years and you can see that here. These are just numbers -- all these slides will be just numbers and not incidences. Despite the decline in size of the population of the Air Force, the number of women has been relatively consistent. You see among injured stratified by the fiscal year, the decline in reporting of sports and rec injuries has pretty much mirrored the decline or the shrinking of the force. And again, constant numbers in women which match our distribution.

Now we will look at some of the interesting -- I think anyway, being an epidemiologist -- things about the sports and rec injuries. Basketball has declined slightly, or I

should say it has matched our shrinking force. These are just counts again. And they can stratify it on the sex. You can see it is certainly more popular for males -- basketball. There is some seasonality. This background noise probably represents what goes on indoor all the time, the pick-up games and so on, and the spike would be the squadrons competing. Age distribution for just basketball relatively mirrors our populations distribution.

We can also look at what parts are injured, and for the purpose of this group and a few others, I have lumped many of the parts together. I think there are around 100 options or so in our data base, and I just lumped them together. As might be expected, foot and ankle injuries playing basketball are proportionally the most common type of injury for that sport. Among the sports, one of the most representative for broken noses, but a small proportion of all injuries.

On here we have an idea for what is the typical injury like. If we added up all the days of work lost for the 10-year period, it added up to that. But again, remember this is the tip of the iceberg because of reporting bias. So this is

unreliable as far as an absolute number of how many days did we miss due to basketball injuries. But this is probably very close, the average reported basketball injury where the worker missed at least a subsequent workday to his injury. That is about how many days they have missed. If they were hospitalized, that is the average hospital stay. And these, if you wanted to read this later, this is how you -- for all the future statistics where you would see this chart, this is how you would interpret it. Since you have that, I will just skip ahead.

Something else we can use the data with the data base is to not only look at each sport, but we can compare sports. For example, if you wanted to compare baseball and softball, we can see the average time lost per injury for baseball is a little longer than the average time lost for softball, and that is to be expected. 33 baseball hits versus 649 softball hits. Baseball is not -- has been sort of -- I don't want to say outlawed, but has been discouraged in the Air Force over time. Softball remains very, very popular. And over time with the breakaway bases and rubberized cleats and so on, you can guess that some of these interventions may or may not make a

difference. If you wanted, you could look at the injury reports.

One thing that I have -- I have samples. If you would like to look at what data are gathered for these sports and rec injuries. The investigator is charged to get to the cause of the injury. So there is a narrative, the very last item on the report, that is just incredible. It doesn't exist anywhere else. It is even better than what would be on the medical record if you wanted to see it. Because the investigator is charged to try and find out the actual cause of the injury.

If you wanted to compare tackle football and touch and flag football, we could do that too. Tackle football is another one of those where again I don't want to use the word outlawed, but been discouraged. It has declined four-fold since 1989 -- I should say injuries have declined four-fold, and that is probably a direct reflection of decrease in playing of tackle football. Touch and flag has declined also. Again, this count sort of reflects our shrinking force more or less.

We were understanding at the Safety Center that tackle football was pretty much not

allowed at all anywhere, so we wanted to find out where these people were getting hurt. When you look at these bases, only the green stars are bases that reported injuries in the United State. The academy, of course, and all the rest are in Europe. You see Germany, United Kingdom and so on. And now, most of these European bases are closed. Statistics on tackle football, the average injury, time lost, longer than the touch and flag as would be expected.

We wanted to lump together just some motorized toys. Here they are. We have had some fatalities with those. By the way, the injury categories would be lost work day, permanent or partial disability, permanent total disability and fatal. Those would be the four only. So this category, if you will, all four you will see represented -- 7 fatalities.

Over time if you were to plot on our declining force, we would expect the count to be going down like this, so this relative stability or perhaps slight increase might represent a true increased incidence of reporting of injuries related to motorized toys.

We wanted to look at snow skiing and snow

boarding. We did have a couple of fatalities associated with skiing and serious injury. And for snow boarding, 71 hits over the 10-year period versus 479. Again, you can't count on the absolute numbers, but the proportion is probably likely accurate with the exception of one thing, which is that snow boarding is, of course, increasing in popularity. And we see that here. Snow skiing injuries declining faster than our shrinking force counts, and snow boarding injuries increasing. So probably the same number of people are hitting the slopes and we see more people snow boarding versus skiing now.

Seasonality, of course, to snow skiing. And I wanted to point out the male age distribution matches proportionately our force make-up. Over-representation, one, not only of females, because we are only -- for the 10-year period, we have only been 16 percent females and this is roughly 35 percent or so. So over-representation in females and a disproportionate age distribution. So is this a reflection of increased popularity of skiing in women or increased risk to injury for women. And when you drill into the sports and medical literature, it looks like women are more prone to skiing injuries.

So this is perhaps an area to target some prevention during pre-skiing season. Just pointing out an example of how we can use these data.

Another interesting thing if you are an epidemiologist female and a sports physiologist, the parts of our bodies that we injure snow skiing -- knee injury is very high proportionately, almost 40 percent of the injuries are knee injuries. Back and spine are 11.7 percent. Compare this to snow boarding, just 4.2 percent are knee injuries. When you think about it, that kind of makes sense. Our feet are buckled into that solid board and our knees are not allowed to flail apart so much. A higher proportion of back, spine, head and neck injuries. The highest proportion are what I want to call landing injuries -- breaking a fall with the arm and so on.

Military people tend to hurt and kill themselves in automobile accidents and in the water. And this is not because we are military, this is because we are people. And in fact, if you look at the incidences of water injuries, drownings and car crashes, the expectation of lives lost would be higher, and especially considering that we are mostly

young and mostly male. You know mostly young males are at risk for fatal car crashes. The expectation of lives lost would be higher than we actually experience. So this is good news.

Anyway, these are the activities that I lumped all under injuries in water. Over-represented by water skiing injuries. Second is swimming and wading. But if you look at lives lost, water skiing falls down to just one fatality, and I believe this one was an impact or crash injury. Many of these are not only drownings -- by the way, most of these people if in fact not all of them who drown did not have a personal flotation device as you would expect. But some people were lost in a crash, a boating crash or a jet ski crash, so the impact killed them and not necessarily the inability to swim away.

Running injuries surprised me because there is a sharp decline over time in running injuries. I thought, why would this be? And for those of you who don't know, the Air Force switched to a cycle ergometry fitness test and we sit on a stationary bike and peddle and we are on a heart monitor to do our fitness test. We used to have to run a mile and a half in X period of time based on

our age and sex. So I wondered if this might have anything to do with it, but you can't tell with the reports. You would have to guess at something else. You see the sex distribution with a little bit of over-representation by females, because again we were only about 16 percent female on average for the 10-year period. So again, we note this decline. I thought, well, we can't get that answer but maybe if we look at bicycling that might help support this guess that people quit running so much after our fitness test changed. And in fact, when you look at bicycling injuries, the count has stayed relatively stable to a slight decline. So perhaps it is because we don't have this running requirement any more. Over-representation in females slight -- very slight.

The seasonality of running is pretty much constant. Over age distribution, it is disproportionate in males because this spike should be higher, and again in females. If you drill into the sports medical literature, this is to be expected. So this isn't a military thing, this is a human thing.

Bicycling the same thing. Disproportionate age representation compared to our

force and the same with the women.

We lost some people hiking. Here were the activities I lumped together for that. I just wanted to show you that quickly. 9 to 14 were falls from great heights. Three were caught in landslide or flash flooding. And where might these people have been recreating? These were the bases they were assigned to over the 10-year period for just the fatal events -- Colorado, which might be expected, and California scenic areas, in other words cliff areas.

Hunting injuries, some fatalities and severe injury. This one I still kept -- it wasn't a motorized toy injury because his primary activity was hunting and I did not duplicate any of these. He was an 18-year-old and he was crushed, but the others were killed by a gunshot, for example. Seasonality of hunting as would be expected. Very disproportionate age distribution compared to what we are, a high score distribution. Parts injured -- these were back injuries mostly from lifting and carrying their gear. I will get to these in a second. Other than these, the rest were typical hiking, walking and sightseeing injury, except again

for hurting the back because they are carrying or dragging the gear.

This right here, this was seen nowhere else. I did a medical search on this and I haven't found it. If some of you have, please let me know. People falling from lookouts hunting. 40 percent of our injuries are that. So this is definitely a clustering and something we should work out and get the word out pre-season. The rest were accidental deaths.

When you think about it, hunting as we saw is definitely seasonal and probably just a small proportion of people do it. So this is really -- when you think about that, how seasonal it is and how few people might really hunt, this is definitely a cluster. Yes, ma'am?

AUDIENCE MEMBER: Is there any -- looking into alcohol-related aspects.

MAJOR CARR: Excellent question. The folks are charged to, if they suspect alcohol, to do a BAT. I will get to this at the very end. The safety folks are not trained at all in medical surveillance, so they say I don't think alcohol was suspected, and therefore I am not going to test. What

the mentality should be is I want to prove or disprove alcohol involvement and therefore I will test. So we are having a hard time switching that mentality. We know with most hunting injuries, they will not even go there.

AUDIENCE MEMBER: And the water sport injuries as well?

MAJOR CARR: Correct. The same thing. The car crashes are different because there is law enforcement that usually helps there. That is a big unknown.

Firearm use and injuries -- in light of everything else going on right now in the country, I wanted to just look at accidental injuries associated with guns and gun paraphernalia. These were, again, not double counted. These were people that were just hurt and that their primary activity was something other than hunting. All kinds of serious injury and fatalities. Here are the activities that I lumped under that -- didn't know the gun was there, a ricochet, putting away the gun, gun bouncing around in the glove compartment of the car and discharged. Just all kinds of inexperienced, unfamiliarity kinds of accidents. There is a seasonal peak that mirrors

our regular hunting season, and this peak I asked the hunters and they said, well, that is bird hunting season. But when I look at some of the reports, not all of them were necessary shots associated with bird hunting. What I am guessing as I look at the reports is this background, if you were to draw a line there, that is the unfamiliarity with the gun and didn't know it was there and unfamiliarity of its use. And this may be the true clusters that are associated -- hunting, cleaning the guns pre and post-season and so on.

Disproportionate age distribution. When you saw the hunting, older people were represented. This type tends to be mostly inexperienced gun handlers. Again, it mirrors our force. Here you see the working fatalities. Again, those are in your notes. I don't want to hold you too long.

Loss of life and serious injury associated with livestock. These are the things I lumped together. Some people hurt on mechanical bulls and camel writing. A spectator got hurt at the rodeo. Some seasonality and over-representation by proportion of females. Most of the female injuries were horse associated. Most of the male injuries

were rodeo injuries. Of the rodeo events, 81 percent were associated with bull riding. And again, if you drill into the sports medicine literature -- once you identify things, you can drill into that literature and find out this is to be expected. This report did not say whether the dismount was premature.

Weightlifting -- I wanted to look at that because we know that is, like basketball, indoors and year round and so on. So not necessarily a seasonality there. Age distribution looks exactly like what we are. Head and neck is fine and back injuries are over-represented. When you look at this cluster and you tear it apart, 62 percent of those are lower back, again as might be expected with weightlifting.

So very, very quick, the idea you can get from using this data bank. I talked a little bit along the way about the expectations of a population-based surveillance system. None of these seem to be out of the ordinary -- proportion-wise I should say. In fact, we seem to be injured less because we are military. What I mean by that is we have -- for example, Services sanctions or sponsors so many of these events. They have referees out there to ensure

that the bases are breakaway and perhaps they will inspect the field and make sure the gopher holes are filled. They won't let people play without their safety equipment. They will look for drunk and disorderly and eject them. So we may not appreciate the forces at work there and we may not appreciate how much contribution these Service-sponsored events do, but they are definitely of value. So that was what that was about. And also, the virtue of this safety investigation. When somebody gets hurt and the safety folks go out there and get to the bottom of why the injury happened. If somebody was wearing improper footwear, it will be logged. I just have a feeling -- you know, it makes sense that somebody is not going to wear the wrong shoes twice. Once they get told, they are going to change.

So safety sees this whole sports and recreation reporting system as an absolute eyesore. They have been wanting to get rid of it forever and the momentum was strong before I got there two years ago. I have tried to convince them this is a valuable -- reporting these statistics and so on was very uninteresting to them. They are trained such that, hey, I need to be able to work on something

where I can make a recommendation and change it. So much of this sports and rec stuff is absolutely out of my control. What I tried to convince them is the reason that is all they are seeing is because they have made that difference. And just as of Friday -- I was going to come and tell you that the sports and rec reporting was going away, and last Friday they had a corporate meeting or policy meeting where they decided, okay, we are going to keep it a little bit longer. But I wanted to bring it out to you because it is always the first thing they want to get rid of on the chopping block. And if we can partner safety and medics together and help make them feel more entrenched and let them appreciate what value they are doing to all the Services and not just for the sake of the total force and for the medics. We can hand-feed the medics this kind of information to target prevention and also recognition for Services. I think the three groups working together can do a lot to protect the total force.

As I pointed out along the way, the true incidence is elusive. But as you can see, you can do lots of comparative stuff by sex and by age and by year and so on. Questions?

DR. PERROTTA: Are there any questions? Dr. Baker?

DR. BAKER: I just wondered in the future with this data, can you separate out those injuries that might be under control or influenced by Air Force policies and practices? In other words, do all the softball areas have breakaway bases? That would be just one example. Can you look at where the softball -- I mean, whether you have sliding injuries sliding into bases. Because those typically involve non-breakaway bases. It seems to me if you could -- I mean, the rodeo things are interesting, but I can see where the Air Force would say we have no control over whether somebody is riding a bull or falls out of a deer blind or something. But many of these injuries are occurring on Air Force property and might be modifiable through Air Force practices. And if you could focus on those in one of your reports, it might help to ensure the future of this data base.

MAJOR CARR: I don't know if most of you heard that. She is talking about the safety issue -- the safety equipment, breakaway bases and plates and so on. The investigator is supposed to go out and make sure that is or isn't happening, whatever the

policy is per base, and it does appear that most of that has been absolutely -- you know, they are all breakaway. Occasionally someone will not check the field and I will stumble on a gopher hole or something like that. But they appear to be doing a great job with that. I hope that safety appreciates that that is the value they are adding. It also is up to the investigator to have even brought that up. Just because he or she didn't mention that, that doesn't mean it wasn't there. That is the other thing we have to live with.

DR. ATKINS: How standardized and computerized are the investigations and reporting? I mean, are they -- do the investigators have a standardized assessment for looking at risks -- you know, contributing factors, and does all that data have to be then entered by someone else? Are there ways to make the system more efficient by having on-line reporting?

MAJOR CARR: The question is about doing the actual reporting process. Excellent question and excellent point. There is a computerized version now where the investigator at all these bases -- and it would be a different person every time -- will be

entering this and the idea is it will go right into the Safety Center's data base. Right now it goes to a data entry person who has been doing this for a long time, and she makes several calls. That is good and that is bad. What is good about it is she is consistent. What is bad about it is that she is not medically trained and so on. She is just an inputter. And because of her own experience, she has gained a lot of knowledge. So now when we go to this big computerized system, everybody in the field will be doing this. So we are trying to reorganize, if you will, the data system, and we are down to just these 15 fields. So rather than make it more selectional with some of these activities, we are hoping to rely more on the scenario, which is good and bad again, because it means you will have to be reading more narratives to find out what really happened, but it is the best way for accuracy.

I didn't copy them for everybody because I wasn't sure of the interest, but I have copies of dummy reports where I have just deleted the names and Social Security numbers, if you would like to get a copy of the reports. I would be happy to do that. Yes, sir?

DR. LAFORCE: How do your rates compare to a college population? I want rates.

MAJOR CARR: Excellent question. Yes. I have looked in the medical literature because I want to know this. Are we over-represented or not?

DR. LAFORCE: Yes.

MAJOR CARR: And by all accounts -- I looked at high school populations and high school populations who play sports, collegiate populations, and then among those who play. And we appear -- what I don't know is what proportion of Air Force people, for example, really do play. If you just take a guess, it appears that we are less injured than those collegiate activities, and that may be because we are more seasonal and we don't have preseason training and that kind of thing. I know the book was written about the hidden epidemic on injuries, but I cannot say that we are more prone than another population.

Another thing this question brought up -- I called the Centers for Disease Control and said is there another population-based sports and rec injury surveillance system that exists that I can look to, and it doesn't exist. The CDC would love to have this. Universities are coming on line -- you know,

the insurance programs at the Universities, and I thought maybe this would help. For those students who have student insurance, they can say how many got injured with sports and rec. Johns Hopkins doesn't even have it yet, but they are saying in a couple of years they will. So we will be able to compare ourselves to at least the collegiate population. And that is not a bad comparison because we are similar in age. We are over-represented with males, but we can sex adjust.

DR. PERROTTA: Carol?

DR. RUNYAN: I have a couple of questions. One that follows up on that one. Is there any mechanism to try and develop some of the exposure information that you have alluded to a number of times, not knowing what the level of participation is or the hours of participation? Are there some mechanisms that might allow you to do that even on some special studies basis?

MAJOR CARR: Gosh, I am certainly open for suggestions. The ones I have thought of, of course, would be doing a survey. And I wonder if the health promotion and public health people -- you know, the medical departments can help with this.

Because, again, the safety -- they are just absolutely not trained at all. By the way, we are trying to help get some medical surveillance training in our training bloc to becoming safety people. Can anybody else think of something to do besides going out and doing spot surveys? I guess that is what we will consider recommending.

DR. RUNYAN: Two other things. One was if you could say a little bit more about the alcohol. I wasn't quite clear the extent to which alcohol was measured.

MAJOR CARR: Okay. On these, there is an area for toxicity testing. It is either -- they are supposed to say not tested, pending or that it was positive or negative, and then it goes into what it was positive for. The safety folks, their mentality is I don't suspect alcohol and therefore I am not going to test. Where as medics, we believe the test is to prove if it was involved or not. And getting them to shift that gear has been very, very difficult. They just don't want to go there. It is an invasion of privacy and they don't want to do the testing and so on. It is different in the car crash reports because usually that is a legal issue anyway

with the police there and so on.

DR. RUNYAN: And mandatory testing is out of the question?

MAJOR CARR: Probably the medical people might address that. I know that has come up several times, and it seems to have just dropped as far as enforcement.

COLONEL BRADSHAW: I don't know that it is out of the question. I think it is possible, but I don't think it currently exists in policy. Do you know anything? I don't know about the other Services. One other thing I was going to ask Bridgette. There are a couple of things. One was the issue of rates. I know you mentioned that you don't get the stuff on the weekends and other things, but do you know if there is any way that we could go about trying to get a denominator so that we could get rate-based information? And then secondarily, adjusting it to our population. I know you mentioned several times getting count data and our population is decreasing and trying. That would be helpful when we are doing comparisons.

MAJOR CARR: Sure. I am sure the Safety Center will continue working on that. But I also

wonder if the easier thing -- DMED, of course, does everything not by activity but by the ICD-9 code. It would be wonderful, since that system has the hospitalizations at least, and they could see -- if this is what you are getting at -- what were they doing. Were they playing basketball? One extra field there. But I don't know which would be easier honestly, sir.

COLONEL BRADSHAW: Well, it might be helpful for us to do some -- as you mentioned, some focused studies and we can do comparability across the two systems. But also we may want to look at some of the things -- the questions that have been raised by some of the data that you have uncovered, and then we could maybe do focused studies on those so we can get the real answers.

MAJOR CARR: If I could -- I am sorry, back to this lady's point. After two years of reading these reports, the investigator will often say they may have suspected something, but they don't pursue it. I actually want to stand up and say -- personally, I don't think alcohol is a big problem in people becoming more injured. It just doesn't appear to be there. It may be in small clusters, but

overall I think there is a greater gain in something else.

DR. ANDERSON: Are you able to identify individuals who have --

MAJOR CARR: Repeat offenders?

DR. ANDERSON: Yes.

MAJOR CARR: Reporting of the name and Social Security number has always been involuntary. And what you didn't see on the age and sex distribution -- I don't know if you saw the counts dropped. Only about 60 percent did we actually have sex information and only about 65 percent did we have age information. But again, we probably have the big picture.

DR. ANDERSON: Yes.

COLONEL BRADSHAW: This is Colonel Bradshaw again real quick. Just to follow-up. She asked about the alcohol. Do you know -- you said they don't ask very often, but do you know how often they do test?

MAJOR CARR: When they do the interview process, they will not only go to the individual. They might go to some people who are on the field and whatever. And they will get -- it usually comes up.

COLONEL BRADSHAW: I just wondered if there is a percentage about how often it is actually screened.

MAJOR CARR: Probably -- I would take a guess in the sports and rec non-car crash about 1 percent.

DR. PERROTTA: Let's take one more question.

DR. SOKAS: I had a question -- a comment and a question about the alcohol. One of the comments is that if you do mandatory substance abuse screening or alcohol surveillance on minor injuries, you tend to discourage reporting in most circumstances. So that can be a potential problem. But if you only had it in place for hospitalized individuals, that might be an easier population to target. You go after the more severe injuries and it might be easier to make a routine part of admissions.

DR. RUNYAN: Just one quick question. You mentioned two areas of concern as you were talking. One was the threat that you have felt to the system itself in the last year. And also you mentioned issues about training of the safety investigators. Are there ways that this Board can help with those

issues?

MAJOR CARR: I am sure there will be in the future. I also wasn't expecting to save this on Friday, and I was ready to come ask you if medical wanted to own this because safety didn't. Now that they want to own it again, I will probably jump and try and bridge that. They are trained in civilian organizations. A lot of them have a certified safety specialist degree and so on. They are not military trained. So I don't know how we would intercept that unless it became or once it became a base assignment. But I will look into that.

DR. PERROTTA: Let's take one more. Colonel Engler?

COLONEL ENGLER: Colonel Engler. I just wanted to say, everyone is focused on alcohol. But in actual fact, the use of over-the-counter antihistamines and in the military sedating antihistamines because of cost issues, there is now overwhelming data that if you look at driving performance, antihistamines interfere more significantly than legal drunken and alcohol levels. And you might want to add that issue since it is 20 percent of the population uses them and the

impairment is not conscious to the user. So that in the testing done in the Canada laboratory, most people didn't feel they were impaired, but their driving performance response was as if they were legally drunk.

DR. PERROTTA: Thanks again, Major. I think what I would like to recommend is we have some very smart people in the injury arena, and I think Professor Baker brought you to our attention and encouraged us to invite you. And I perhaps would like to, maybe as a parting act, ask that we continue a collaboration with the Safety Centers, maybe aiming towards more collaboration with the medic side or whatever. I can't imagine that given the size of this problem that most of us would feel in good conscience to watch this source of information, even though some of it we can't do much about or is out of the control of the command line, that we just walk away from it. So I think I would ask that Drs. Runyan and Baker, as you continue on the Board to in-between meetings have plenty of conversations and look for ways that the Board can assist your work, and you do the same with us, using us as a resource. Is that a reasonable request? It is sort of a blind

request.

COLONEL BRADSHAW: This is Colonel Bradshaw. I just wanted to also say that the Commission for Safety and Health Promotion Council has a specific committee on unintentional injury, and we can maybe do a follow-on presentation from them. A former member of the Board, Colonel Defraites, is actually chairing that committee. So we can maybe get a follow-up and work very -- because it does involve both the safety community and the medical community.

DR. PERROTTA: Right. And part of the report suggested that we have useful data bases on both sides and never the twain shall meet. And I think we judged that as a problem way back when. So there may be improvements now, but whatever we can do.

AUDIENCE MEMBER: Can I just say it would be very helpful to not limit to unintentional injuries. Half the military deaths are accident, but a quarter are suicide and homicide, and those are just as much injuries as are unintentional. From a system standpoint, any death is unintentional.

DR. PERROTTA: Perhaps we -- as a matter

of fact, I may be imposing on the leadership after me, but I have not heard enough in my personal experience of six years on the Board -- heard enough about suicide and homicide on this Board. So maybe I could convince Ben to put item number 6 down there for consideration. We have heard some, but given the extent of the problem in the general public as well as in the military, I think that would be useful. I will leave it at that.

Debbie Maiese is the team leader for the HP2010. She is out of the HHS Office of Disease Prevention and Health Promotion. She is going to visit with us on Healthy People 2010. A reminder to everyone to please use the microphones if at all possible as you address the speakers.

MS. MAIESE: Thank you very much. I think I will actually even do my own overheads today. In the time that I have with you, I would like to review our experience with a framework of national health promotion and disease prevention objectives. Something that we have been using in the U.S. Department of Health and Human Services for the last 20 years, and give you a preview of what is to come over the next 10.

It really is a very data intensive framework. One of the slides that I didn't bring with me often shows healthy people as a little house with data and surveillance systems in the foundation. What I thought I would do is begin to sort of show the evolution of this framework over the past 20 years. This really began as a Surgeon General's report in 1979. Julius Richmond of President Carter's administration released for the first time ten-year targets. It was the first application, if you will, of putting a forecasting tool into health promotion and disease prevention.

There were five targets set, four of which focused on reducing premature death, and the fifth was focused on preserving independence. Those goals of healthy people have really metamorphasized. Now, for 2000, we are looking at increasing the span of healthy life, a very difficult thing, I might say, for us to measure. We have been using some summary measures from the National Center for Health Statistics looking at life expectancy and the percent of those life years that are separated as excellent, good or fair as well as separated in activity limitations.

The second goal of Healthy People 2000 looks at reducing disparities among population groups, gender, or socioeconomic status.

Our third overarching goal focuses on increasing access to clinical preventive services. We maintain the age-specific targets that started this initiative.

For 2010 -- and please notice that we are calling this the 2010 draft, because 2010 will not be launched and officially released until January of next year -- the emphasis here has been on maintaining the first goal of increasing the years of not only healthy life, but the American people said to us in this 1997 public comment period that they wanted to focus on quality of life years, again a tall order of how we are about to measure not only years of healthy life but the quality of those life years.

You'll notice how we benchmarked the second goal to a higher standard. Not just reducing disparities, but the elimination of health disparities, and I will dwell on that a little more later.

The access to clinical preventive

services has really now been embedded in a number of different chapters, and so we don't show it as a goal.

Some of what has happened over this two decades has been increasing participation, public participation, in this process. When this all began, it was really a scientific conference in 1980 that looked at those five life style targets and said what can we do with disease prevention and health promotion targets. And out of a conference that was held at CDC with about 200 participants emerged the first national health promotion and disease prevention objectives. A Federal Register notice solicited comments, but actually because of a change in the administration, there was a sort of a hurry and get those 1990 targets out. So there wasn't a very -- it was really an abbreviated public comment period.

The Healthy People 2000 development really was a three-year development period beginning in 1987 with the Institute of Medicine inviting for the Public Health Service some 187 national membership organizations -- the American Hospital Association, the American Medical Association and

others to join in the healthy people consortium. All state health departments and territorial health departments were invited to join this consortium, and they were very active in public hearings and commenting on this framework of objectives.

For 2010, this consortium has more than doubled in size -- 350 national membership organizations ranging from the Girl Scouts and Boy Scouts to the Association of Retired Persons and a lot of civic groups as well as those in the health professions.

One of the things that we did to begin the 2010 development was the 1996 Commission of focus group process where we asked our stakeholders to evaluate what had worked in Healthy People 2000 and should be preserved and what hadn't worked and needs to be recast. I might add that that stakeholders report and in fact every product that we have produced since 1995 is up on the Internet for all to use.

In Healthy People 2000, there was one public comment period, five regional hearings, and about 350 participants. In 2010, there were two public comment periods. Again, asking in the first

public comment period about the goals, the framework, and the extent to which we needed to recast the objectives. In 1998, we actually published this 2010 draft and took public comments through five regional hearings and through the Internet directly. We consulted and got more than 11,000 public comments. Thank goodness the technology has kept up with the volume of input that we have had. Because actually all of the public comments that we received are on the Internet and they are completely word-searchable for all of you to use.

We then show as a result -- perhaps again as a direct result of this increasing participation in this process, we can watch this framework expand from 15 chapters that were called priority areas when this framework started with 226 objectives to 22 priority areas that we pursue in Healthy People 2000. And for the 2010 draft, there were actually 26 priority areas and we have now added two more as a result of public comment.

Let me just give you a flavor for some of the subjects and the expanding areas of this initiative. Between the first and second decade, we added some of the chronic diseases -- cancer and

diabetes. We began to get into some of the infrastructure, such as education and community-based programs. That is where we put the healthy schools and the healthy workplace objectives. Food and drug safety was added to this initiative in 1990. And HIV infection, of course, wasn't even on the radar screen when this began in 1979. Surveillance and data systems are a set of objectives that we have now embedded in a new chapter called the public health infrastructure for 2010.

Again, to give you a sense of the increasing focus and range of subject matters covered by Healthy People, more chronic conditions -- arthritis, osteoporosis and chronic back condition objectives are being proposed for 2010. A new chapter on disability and secondary conditions focusing on disabled people and closing that gap in their labor force participation and in their health status and so forth. Health communication -- again, an interesting and new domain looking at what happens in clinical encounters and the kinds of information that patients say they are getting. The quality of the information on the Internet. New subject matters that we are trying to address in health

communication.

Public health infrastructure becomes the place where we are monitoring work force, research and resources, and of course surveillance and data systems. A whole new set of objectives. And respiratory diseases, where we really focus on asthma and COPD.

New focus areas that were added as a result of public comments. There was a tremendous outpouring from nephrologists, renal patients, and great debates within the Department about moving this agenda. And one of the things you can see from this expanding focus is we moved from a primary prevention focus to now addressing secondary and tertiary prevention activities as well. And that brings us to introducing chronic kidney disease to this framework as well as the new chapter on vision and hearing.

There has also been an evolution of these chapters. David Atkins is here with us today. He is one of the work group co-leads on this access to quality health services chapter. The Surgeon General has designated lead agencies within the Department of Health and Human Services for each of these focus areas, and we have actually reached out beyond the

Department and have invited the Department of Education to co-lead the disabilities chapter, in part because they are the data source for so many of them, and we have also invited the Food Safety and Inspection Service of the Department of Agriculture to co-lead the food safety chapter.

Let's dwell for a moment on how even the chapter has metamorphasized. Originally this was the clinical preventive services chapter. When we all met in Indianapolis in 1997, the objectives really focused on primary care and clinical preventive services. But as a result of a process and consultation from a number of the stakeholders, this chapter has evolved to include now emergency services as well as long-term rehabilitative care services. We have separated diabetes from disabling conditions and separated food and drug safety as well.

To a sense -- particularly in front of this epidemiologic Board -- is Healthy People has been a data driver. As we introduce these new subjects, we really don't shy away from the fact that we are also going to explore new subject matters and thereby present new data challenges. And we are calling these objectives that have no national

baseline as developmental objectives for 2010. You can see they have really always been with us from 1980 to 1990, a third of the objectives. I have to say in that decade there really wasn't a lot of progress in getting things measured. In fact, about 23 percent of the objectives in the first decade were never measured. Whereas with Healthy People 2000, we have measured all but 9 of the 91 that were originally without any baselines. So Healthy People has enabled us to go out and do primary care provider surveys about the extent to which counseling and assessment goes on in the clinical encounter. It has helped us field a new school health program and some practices surveys looking at what is done in school health education and in physical activity in the schools. And the third domain -- and in fact, later this week the Association for Work Site Health Promotion will release an update on our work site health activities. Those things that are happening in the private sector in work site health promotion.

So we don't shy away, although these numbers we continue to work on with Healthy People 2010. We are down to less than 500 objectives and more closely like 35 percent of these objectives are

developmental. We really are challenged about the data development that we are proposing to the American people.

Let me also talk a minute before I leave this slide about the impact the data has, and let me just use one set of objectives. That has to do with provider counseling. As I mentioned, the clinical survey that is done by the Office of Disease Prevention with our partners was attempted to be replicated by the American College of Preventive Medicine in 1997. But physician response rate was so poor in this survey that we were unable to use the results. As a direct result of that failure of physicians to report on the extent to which they are assessing and counseling, we retooled those objectives and thanks to David Atkins and a lot of work has been done to recast those objectives for 2010 and to look at it from a patient's standpoint. We are no longer going to look from a provider's standpoint. We are going to look at the extent to which the American people said at their last clinical encounter the physician or the nurse practitioner asked them whether they were a smoker and in turn counseled about cessation. So it is a really

interesting thing, and of course time doesn't permit to give sort of all of the stories, let alone the war stories that go on in this sort of evolution of these objectives.

Let me deal with one other really significant development between Healthy People 2000 and Healthy People 2010. In fact, when Healthy People began, there were no subobjectives. There was only one national baseline and one national 10-year target. Healthy People 2000 began to introduce special populations. In essence, where there was a known disparity or there was a breakout by race or ethnicity or by gender or socioeconomic status. And the target was set on a realistic basis and rarely the same as the national average, with a few exceptions in some service objectives.

For Healthy People 2010, as the Surgeon General began to do progress reviews for Hispanic Americans using these objectives to look at how we are doing in improving the health of Hispanics, they said to the Surgeon General and the Secretary for Health, we don't like this disparity in targets. We want one target for all population groups. The Secretary's Council chaired by Donna Shalala with

Surgeon General David Satcher as the Vice Chairman said we agree that eliminating health disparities in this country should be where this rich nation proceeds over the next decade. So we are setting one target based on the President's race initiative in a number of domains. We are also saying that the smoking prevalence rates should be one for all population groups among services, be it mammography, pap, immunizations -- one target for all population groups. And with outcomes, we hold our breath and say it is really not possible to make that much progress in a decade. So there were exceptions to this target in the long-term and in particular chronic disease.

To give you an idea, just to switch gears for a moment -- to really give you a sense that Healthy People is a consensus building process. And for those of you who work in installations around the country, we really did hear from people in every state in the United States as well as from Puerto Rico and Guam. We also heard from some international colleagues about this framework. And I would encourage each of you to look at these comments. Let me give you the web address. It is www.health.gov/healthy people. What is really

amazing is the draft document itself was key word searchable. All of the public comments -- although about half the public comments came in on the Internet, the other half that was paper comments, even the handwritten ones were typed in and keyed into this data base. It is a complete repository. If you want to look at injury prevention, you can type in the word injury. If you want to see who commented from Maryland, you can just type in the word Maryland. It is a really powerful and amazingly quick tool.

To give you a sense of the kinds of comments we got, interestingly the access chapter got more than 1,200 comments. But these are examples of the chapters as we proposed them that got more than 500 comments. In education and community-based programs, we heard from school health nurses around the country about the ratio of school health nurses to students. In the nutrition arena, we hear a great deal about obesity, particularly obesity as a separate focus area and debated hard and long in our Healthy People steering committee about keeping obesity linked to nutrition. Maternal infant and child health, a lot of focus on children with special

health care needs, and a great deal of interest in this country on injury prevention.

Let me share with you a minute on how we are doing on Healthy People 2000. This is what the report looks like that I am about to give you the results of. The pretty purple color doesn't quite show up. Dr. Satcher actually released these results at the Harvard Medical School commencement in June. He was accompanied by Julius Richmond, the first Surgeon General who released and is the founder and father of Healthy People. It was really interesting that several people sort of took pause at the fact that we had only achieved 15 percent of our targets at this late date in the decade. But I need to remind everyone that in 1995, we did a mid-course correction and about 85 of the targets that had already been met in the midstream were made more challenging. So we continued to use this as really a driver of action.

Of those 15 percent of the targets that have been achieved, some really good news. We achieved the child death reduction. And for the first time in this initiative, we have achieved the adolescent death reduction. Most of the cancer

deaths are right on target. A lot of progress in cancer and in heart disease. We have made significant progress and hope to go over the top in areas like prenatal care and mammography screening. But there are the challenges. I think as Dr. Satcher uses this framework in these progress reviews, we always talk about these challenges, particularly those with data where we haven't been able to make the assessment as well as those that are going in the wrong direction. And some of those examples that this audience probably knows very well is the increasing of overweight and obesity in this country, not only among adults but among children, asthma hospitalizations, child abuse. The topics are throughout Healthy People.

As I talked with our colleagues from the UK at the break, I asked the extent to which they use their For Our Healthy Nation in the military and armed forces in the UK, and he said we are picking and choosing. Well, I propose to you that Healthy People is a full menu here in the United States. That is certainly something for you to pick and choose among.

Let me share with you where we are this

year and where we are headed in the next year and beyond. Certainly our work groups have really been hard at work the first few months dealing with these 11,000 public comments. I actually had an intern who sort of looked at the extent to which the additions outweighed the mergers and the deletions, and it was something like 7 to 1 was the ratio of people saying you need this subject and that added to this framework. Our book is quite more a weighty tune than the red book that you were given this morning. But we are certainly grappling with trying to balance this comprehensive set of objectives with a leading health indicator set. Something like 10 measures that can become sort of a public health report card that is more user friendly and something that perhaps the Surgeon General and his prescription pad can give out to every American to say these are the 10 most important things you can do for health promotion in your own lives and for your family.

The other thing that we are really hard at work on is really helping states and communities to replicate this framework. We just released a Healthy People 2010 tool kit that is up on the web. And again, it shows lessons learned and best

practices, not only from the national experience but from state and local domains.

I invite all of you to join us on January 25 here in Washington, D.C. at the Omni Shoreham. The pamphlet that I brought gives a listserv that you can sign up for to get more information about our conference. That is when we will debut Healthy People 2010. So please join David Satcher and the Secretary in helping us to launch this framework that we hope will drive an action.

We are also looking towards Public Health Week. And I don't know the extent to which the Armed Forces have really joined the public health community in using that first week in April as an opportunity to once again showcase prevention. But Dr. Satcher in last year's series of audio conferences with the states getting started with 2010 really encouraged them to use that Public Health Week as an opportunity to set forth their own objectives. And again, the local adaptation and adoption of these goals is really where the action is.

I would also suggest to you to get companion documents. Taking these objectives and packaging them for your own use is again an opportune

way to really use it as a data driver, use it as an opportunity for promoting healthy communities on military installations, as well as in clinical practice in the military health system. There are countless ways that we could talk about packaging Healthy People for your use. And why don't on that note I stop and take some of your questions.

DR. PERROTTA: Thank you. Do you have any questions?

DR. HAYWOOD: What are the budgetary implications?

MS. MAIESE: Budgetary implications. Healthy People is actually embedded in three Congressional statutes. The first is the Maternal and Child Health block grant. The second is the Preventive Health Services block grant. And the third is in the Indian Health Care Improvement Act. So Native American/Indian Health Service. In the first two, it is the framework for states to monitor and report to Congress on their expenditures under the block grant. In the third, interestingly enough, Congress was very prescriptive and picked 65 of the Healthy People 2000 objectives and asked the Indian Health Service to report on those.

We are working on -- and I don't know how at liberty I am to say it -- but certainly the Secretary herself at the Secretary's Council meeting in April talked about using Healthy People as a framework and an emphasis in HHS budget for 2001. So the timing of this release, you might notice, is a week after the State of the Union Address and a week before the 2001 budget goes to Congress. So we are really hard at work on a health promotion and prevention theme for 2001.

DR. HAYWOOD: But the access issue is not going to be solved without a big increase in budget.

MS. MAIESE: That is one perspective no doubt. And clearly money can help. But we all know, and certainly evaluation of Medicare -- and I just use older adult influenza vaccination as a case in point. There is an example of where we have universal coverage on a benefit that has really been highly promoted, and yet that is one of those targets, while moving in the right direction, we haven't achieved for Healthy People 2000. And so we know that there are barriers beyond just the access issue that we all need to be working on in health promotion.

DR. PERROTTA: Other questions?

DR. WEINSTEIN: I have a rather naive question. Some of the most important objectives are going in the wrong direction. I am not sure how this whole system works. Who has responsibility for meeting these objectives?

MS. MAIESE: Well, it is a shared responsibility. In part, the lead agencies have the responsibility to help monitor and report. And so even just the monitoring and tracking of this and the extent to which we have supplements to our national health interview survey and other vehicles for collecting this information is something of a shared responsibility among the lead agencies in the Department of Health and Human Services. But we also look to members of our Healthy People consortium. And clearly they are the intermediary to their memberships and to their constituents and to the American people to help us get out the messages about eating 5 fruits and vegetables a day or reducing saturated fats in your diet. So it is a big distributive process. And this sort of becomes a sheet of music that hopefully we all get on the same page about. David, do you want to help me with that?

DR. ATKINS: Well, you should just point out the leading health indicators as important. They have chosen a set of -- I will let you describe it, but a more targeted set to give added emphasis to really critical issues within over 500 objectives.

MS. MAIESE: That is right. So we have been through a process with the Institute of Medicine looking at -- and Nicole Lurie, who is Dr. Satcher's principle deputy, went before the IOM and said please don't give me any more than those I can count on my hands. So we are hoping to focus on those critical issues in health. We certainly are about to go through clearance with this document, and it will be shared with DoD for review as well. And until they really are through the clearance process, I think we actually may be waiting until the release on January 25 to release what those 10 critical indicators are.

DR. SOKAS: I mean, just to sort of respond to that question as well. There is a carrot and a stick approach. If this is what the Executive Branch of government feels important, which is basically what this is, then, for example, if asthma is targeted, then there might be more research emphasis or more IOM studies commissioned or whatever

on how you would do it. So that is kind of the way they try to move it forward. It is not so much there shall be regulatory activity that says you have to do this or that.

MS. MAIESE: It is a range of objectives. I mean, there are policy ones that are legislative. For example, there is a tobacco tax objective. So there are things. Or indoor air quality that monitors access to tobacco and enforcement of those minor access laws. There are certainly the individual behavior ones about exercising, moderate and vigorous, and breastfeeding newborns. It is a whole menu of objectives.

DR. PERROTTA: Any final questions? One back here?

AUDIENCE MEMBER: Doesn't the military also -- are they going to have their own version of 2010?

MS. MAIESE: I don't know the answer to that.

DR. PERROTTA: Dana?

COLONEL BRADSHAW: Not at this stage, no. We have attended some of the consortium meetings and also saw the progress reviews. In the sense that we

are attempting to put prevention into practice and meet some of the -- we use some of the Healthy People 2000, for instance, objectives to kind of look at benchmarking PPIP where those match up. So in that sense that we are doing PPIP, we kind of look to that as one of our ways of benchmarking along with HEDIS standards and things like that, sort of the PPIP objectives. I don't know, do we actually have a DoD -- you said you had state and local groups. Do we actually have a DoD? Because I am not aware that we do.

MS. MAIESE: No. The consortium has really been outside private sector organizations, not a federal interagency body. We grappled with how do we bring our partners in, and I think certainly it has been on individual work groups, be it clinical preventive services or perhaps injury prevention. So the lead agencies draw in the Armed Forces to participate. But the extent to which we could do it better I think is always, and the extent to which we could certainly see this sharing and the extent to which the targets are adopted by the military in particular domains to help us promote this as a national consensus about the direction and what it is

possible to achieve over the next 10 years, we would welcome that.

DR. PERROTTA: Okay. Thank you, Debbie, for coming. It sort of brings me a little bit better up-to-date.

MS. MAIESE: Thank you.

DR. PERROTTA: Next we have the 1998 survey of health related behaviors among military personnel. Not an unrelated presentation by Dr. Bob Bray, who is at the Research Triangle Institute. Thank you for coming and addressing us, Dr. Bray.

DR. BRAY: I appreciate the opportunity to be here and share with you what I think are some pretty exciting and informing results from a series of DoD surveys that have been conducted over this past 18 years, with a special emphasis on talking about some of the results from the 1998 survey.

Hopefully, these data will provide an empirical foundation for addressing some of the program needs to help encourage and improve positive health behaviors among military personnel.

The focus of what I want to cover very quickly today will be to look at some prevalence and trends in substance use. Look at some issues of

alcohol, illicit drugs, tobacco, and give some comparisons on these with civilian data. I'll talk a little about mental health. And then a nice follow-up to the presentation we just had, to look at where the military has gone on just a handful of Healthy People 2000 objectives. Talk about just a few additional special issues and then a little bit of a wrap up.

In 1980, DoD Health Affairs commissioned a study that was done by Burt Associates which really was targeted as a drug and alcohol survey. I don't think it was ever intended to be a series of surveys as it has turned out, but the findings were so startling and disturbing that DoD subsequently felt like they needed to address some programs and some initiatives and then take some steps to see where they have been since then. That resulted in a subsequent survey being conducted in 1982, and then about every three years since then there has been a continuing survey. As you can see, the sample sizes of these have been very large and substantial, and also this slide notes the response rates for the surveys. There is kind of a disturbing thing going on here. The response rates seem to be inching down

over time. I think that is a function of several things. One is the military is being bombarded with surveys these days. So this is just one more thing to do. The size of the military has been reducing or getting smaller, and as a result there is more demand on time and the survey is one of those things if you can offload it and say it is not critical, then it is one of those things that you indeed say, okay, we won't worry about that. So it is a challenge.

Then there are also issues about how you staff it. It really has to be staffed in the military down the line side. The last couple of surveys have been unfortunately done coming through the medical side, and it just doesn't get the attention as if it goes the other way.

Now there is a lot I can say about how the surveys were conducted. I am going to skip over all that, because I think the results are really the key thing that people want to hear about today. This particular slide shows some trends in heavy alcohol use, cigarette use and illicit drug use. And there are some pretty impressive trends here, all in a favorable direction. The top line shows that cigarette smoking has gone from about 51 percent down

to roughly 30 percent in 1998. Illicit drug use -- the bottom line has dropped from about 28 percent down to roughly 3 percent. And in the alcohol use, smaller declines. It has gone from about 21 percent down to 15 percent. All significant declines over the period, and that is good news I think for the military.

This particular slide looks a bit more at alcohol use. We see two things here. First, the top line shows what has been going on in terms of just general reduction in alcohol consumption. So we developed a measure that kind of has levels of use. The lighter ones are abstainers and frequent light drinkers. And what we can see there is there has been a notable increase in this group. Many more people are now drinking at these lighter levels or abstainers. Heavy alcohol use, we saw that on the first slide. It is much flatter. A little decline, a significant decline. But if you focus on where the decline is coming, it has really come between 1980 and 1988. The last 10 years is pretty flat. Hardly any change at all in the proportions of heavy drinkers among the active duty force.

We took a little bit longer or more in-

depth look at this heavy alcohol problem. One of the things that we have noticed over the last 20 years is the demographics of the military have been shifting considerably. The military today is on average older and more likely to be married and more likely to be better educated and more likely to be female. All of these are associated risk factors with reduced substance abuse. So we asked the question, how much of the decline in substance use might be a function of these changing demographics. So what we did was to standardize the demographics back to the distribution in 1980, and then plot the line. So this upper line shows what these rates would have been expected to look like if the demographics had not changed. As you can see, they have raised. And in fact for the heavy drinking line, what we see is that there is no significant decline between 1980 and 1998 for these adjusted figures.

What that suggests then is that one could attribute most of the change in heavy drinking to the shift in demographics, more so than to any effects of programs or initiatives or efforts that the military has made to try to reduce heavy drinking.

I might say, although I am not showing

this slide here, that was not the case -- we did that adjustment also for cigarette smoking and for illicit drug use, and demographics did not explain away those changes at all. There was still very significant declines for both of those substances.

Cigarette smoking is an area that the military has been putting a lot of emphasis on of late. And this slide really I think is pretty informative about how things are looking in that regard. First off, we see that over half the military are personnel who have never smoked. That is pretty encouraging -- 56 percent. Roughly 10 percent were former smokers who quit over a year ago. 4 percent quit in the past year. So we have got roughly 14 percent that were former smokers who have quit at some time. And then you've got the residual roughly 30 percent who are current smokers.

Now the more interesting part about this is that it appears as though smokers really have an interest in trying to break the habit and quit. We have got only 11 percent of those smokers who haven't made some effort. You've got 46 percent tried to quit and 42 percent who didn't try to quit among that current group. But among those smokers, there is a

lot of interest, it would appear, in trying to break the habit.

I think there is a wonderful opportunity here for intervention and for additional emphasis to be placed on this group. And I think there is a lot more that could be done in this area.

Very quickly, who are these users of cigarettes, drugs and the heavy alcohol. Perhaps not too surprising for those who have been around in the military awhile, but they typically tend to focus on this junior enlisted group, the younger male population. Those who tend to be less educated, single, junior enlisted and so on.

The slide mentioned earlier at least a comment about the cigar/pipe that was mentioned by Colonel Bradshaw. This shows a trend in the use of both smokeless tobacco and also cigar/pipe use. And we see kind of some interesting things here. The smokeless rates, first off, are pretty high. We will see more about that when we look at Healthy People in just a minute. But running around 18 or 20 percent and kind of flipping up and down. Not a lot of real shift there. When we look at cigars and pipes -- and by the way, we don't have the data to separate those

out. We just ask the question, do you use cigars over pipes and now we see we wish we could break it out.

It looks like there has been a bit of a tendency towards declines between 1985 and 1992, a little inching up to 1995, and then this fairly dramatic increase between 1995 and 1998. Almost doubling, going from 17 to about 33 percent. We think most of this is due to cigars rather than pipes because there seems to be a resurgence of interest in cigar use in the nation, and we think that is simply being reflected. The good news here is that the use doesn't appear to be very heavy use. It is occasional use. But the fact that there has been such an increase may suggest an area where more attention should be given.

One of the things that I think the military always looks for is a comparable benchmark. How are we doing relative to some other comparison group. The civilian population has served as a useful benchmark on at least substance abuse data. What we have done is be able to get data from the National Household Survey on drug abuse and then we adjusted the demographics of the NHSDA data to look like the military, that is, make them look like they

are more male, younger and so forth. And then re-estimate how the civilians would look relative to these military data. This gives the information on heavy alcohol use. If you look here at the civilian rates, we have got the two age groups, 18 to 25 and 26 to 55. The military tends to be dramatically higher than civilian, but that seems to be driven by the younger, the 18 to 25-year-old group are really accounting for the disparity in heavy drinking. So the military rate is roughly double. This seems to be fairly consistent throughout all of the Services. The Marine Corps really hit the top there of the group. So very, very much higher rates in the military among the heavy drinking than the civilians.

When we do the same thing and look at illicit drug use, we see just the opposite pattern. The military just completely goes the other way. Much, much lower in DoD than we have in civilian, and that is true both for the younger and also for the older. The military rates are just extremely commendable when it comes to the situation of drug use.

When we look at cigarette smoking, we see again a somewhat favorable picture in that the

civilian rates are now higher than the military rates. Again, this seems to be largely coming from the younger 18 to 25-year-olds. This I might add, is the first time in 1998 that we saw this pattern. Previously, smoking has always been higher among military personnel. So this is some very good news. It is really coming from two directions. The military rates went down a bit, but the civilian rates went up a bit. So kind of a crossover. These aren't huge differences, but they are significant with the military being lower. So, again, that is all good news.

A number of studies have found a pretty robust relationship between mental health and an individual's capacity to function effectively. And one of the things that we looked at in the survey was levels of stress or reported stress among military personnel, as well as some behaviors to cope with this stress. And then we also got some information about depressive symptoms and personal beliefs about mental health counseling on military careers. This shows the rates of stress. As you can see, over a third of those in the military report that they experience either a great deal or a fairly large

amount of stress at work. About 21 or 22 percent are experiencing that in their families.

We then asked them to identify -- or at least we asked what we thought might be some common sources of stress and to rank the importance of those. And what is listed here are the ones that were rated the highest. It is kind of interesting that we asked a separate question of just the women. How much stress did they feel just being a woman in the military. A lot of recent publicity about that, sexual harassment and so forth. Women do feel, I think, some additional pressures. It may come partly from being in a minority status. You know, women only comprise 15 to 20 percent of the force, so they are outnumbered. About a third of them are saying they feel high stress in just the role of the women. One of the other factors here are being away from family, perhaps not too surprising, increases in the workload, financial problems, and so on.

What do they do to cope with this stress? Fortunately, most of them engage in what we might consider positive or productive kinds of behaviors as opposed to the less positive aspects. The large majority are saying that they try to figure out what

is going on and think of a way to deal with it -- talk to people, exercise, hobby and so on. We see a few differences between men and women here. Women, for example, are more likely to say a prayer than men are. Men, on the other hand, say they are more likely to use alcohol. Women are somewhat more likely to get something to eat.

When we looked at depressive symptoms -- and this, keep in mind, is a survey. We are not actually doing a clinical interview that would really pull out a full need to classify somebody as depressed. But our survey questions at least suggest that these people might be in need of further evaluation for clinical depression. What we are seeing here is that there is a 15 percent or 16 percent it looks like overall and that varies a little by the Services, with the Army showing slightly higher rates there. We also -- it is not shown here, but one analysis that there does seem to be a relationship between the higher levels of stress and those who report these higher rates of depressive symptoms.

How did this compare then to people's understanding of what would happen if they went and

got counseling for depression. We asked them whether they thought this would be detrimental to their military career if they got counseling, and the news is I think fairly positive here. Most of them don't really seem to know, and that may simply reflect that they haven't had much experience with either trying to get services, so they don't have much of an opinion of this. But of those that did have an opinion, it seemed to be roughly kind of split. About half and half between those who thought it would be harmful and those who thought it would not. But it suggests that there may be some opportunities here to educate people and to help them benefit from the kind of services that are available.

Now we are moving into Healthy People 2000. This is a selective set. The sets that are presented here really have to do with those that were felt could be measured through a survey mechanism. This was only a subset of those that DoD has attempted to look at or at least identified as valuable.

We don't have time to really get into these in much depth. So what I will do is hopefully have some handouts that show these and show the

rates. The ones that have the little asterisks on them are the ones where the objective has been met. And there is kind of an interesting thing here. The objectives have been met for the overweight, age 20 and older, the objective of 20 percent, and the military is at 19.5. But sort of an interesting thing here. The military has actually increased in -- well, to say it another way, they have increased in the number who are overweight between 1995 and 1998, still fitting within that objective. They also have, no surprise, met the strenuous exercise. Extremely impressive here on the 20 percent goal. Let's see, seatbelt use is another one. They exceeded the 85 percent there. And then the pap smears, either never received or received in the last three years.

Now the interesting thing about this, the places where the goals have been met are places typically where there have been some regulations that pushed people to do it. Places where they have to use their own initiative and say, yes, I am going to do this are less likely to have reached the goal. Although still making some pretty good progress in a number of areas even though the goals haven't fully been met.

Now let me talk a little bit about some of the specifics of some of these individual goals. Here we can see the cigarette smoking, and the goal is the 20 percent. Even though the military has been coming down, they are still roughly 10 percentage points above that 20 percent goal. It seems unlikely that they are going to make that by 2000. This one shows the same thing for smokeless tobacco -- 18 to 24-year-olds for smokeless tobacco. The goal, 4 percent. The military is pretty much off the charts when it comes to looking at that goal. Much, much higher rates running around 19 percent. So we're not even approximating that one.

Overweight -- this is sort of an interesting one. These criteria for Healthy People were different for those under age 20 and then those 20 and older. You know, the goals are different. So there is lots that can be said about this, but less than 15 percent was the goal, and that has not been met by the under 20, by either the DoD level or any of the Services. Now when you look at the 20 and over age groups, the goal was less than 20 percent, and even though we see that the overall goal was met, when you break it out by Services and by age groups,

you see there are considerable places where the goal has not been met. Most likely because as people get a little bit older, they tend to not be as vigorous with the exercising, and so we have a whole problem there. Except for the Marine Corps. There is a commendable example there. Look at these guys. They are way down there. So hats off to the Marines.

Interesting things happen in the overweight guidelines. In 1998, the National Health Lung and Blood Institute issued a new criteria for evaluating overweight. These are using the BMI criteria. They in effect lowered the criterion. What that has the effect of then is making everybody look more overweight relative to what the Healthy People 2000 criteria were. So if the military were to adopt the NHLBI guidelines, over half the force would now be considered overweight by that criteria. That is an interesting thing. The criteria has inched down, and you have a lot of people who are within a couple of points on the BMI, which is forcing them to look so bad with these new criteria.

Blood pressure -- about 14 -- no, let me back up. First the Healthy People asked about lifetime history of high blood pressure. As you can

see here under 20 percent ranging between 15 and 20 overall. But of those, then the goal is to have 90 percent taking some action to deal with that. And the military is not there. It is more approximating about 45 percent. So a big gap between the goal and where they are, even though this is only among a very small proportion of the people.

We have heard some about injuries already. The rate for Healthy People 2000, 754 per 100,000. When you look at that rate and where the military is, the military is very, very much above that. Probably four times that rate. Is that a good rate or not?

Condom use at last encounter among sexually active people, we haven't met that goal. Quite a bit needs to be done there. It is sort of interesting when you look at that one and then you ask or compare STDs. What we see is the need for some more attention there, particularly when you compare men and women. You see the STD rate is higher among women, suggesting an area that needs attention.

It looks very good among alcohol and cigarette use during pregnancy. Even though they

haven't quite reached the goal, very close. One might say there is still some residual group, 14 percent or so, that aren't getting the message and are still failing to take the right actions.

Prenatal care, a similar kind of thing. About 85 percent are getting care in the first trimester. Those who are not tend to be that younger, less educated group who are in need of some assistance there.

For the first time, the survey asked about testicular exams. The National Cancer Institute suggests it should be done about once a month. We find that 30-some percent of the military are engaging in that. What is interesting about this slide is if you look at the places where people have gotten education, there seems to be a relationship between education and the actual behavior. Those who were more likely to get the education were more likely to actually carry out the practice.

The survey asked for the first time about dental check-ups, and not too surprisingly very high rates of people getting that. Although one thing is surprising and not shown here is about 16 percent had reported that they needed dental work before they

could be deployed. That is of some concern. Why aren't people getting check-ups? Well, lots of reasons. Some of those I think could be intervened with to perhaps encourage that over 10 percent.

Just wrapping up what we can conclude from all of this. First has been extremely impressive progress in reducing substance use, less so for the heavy alcohol use. It looks very favorable on the drug and cigarettes compared to civilians, but looks much worse in the alcohol use. Encouraging that about a third of smokers say they are planning to quit in the next 30 days, a good motivated target group. Smokeless tobacco use quite high among the military as well as increases among the cigar -- we think cigar use.

Healthy People 2000 objectives that were met are the strenuous exercise, seatbelts, pap smears, and being overweight, although there are caveats with that. The ones in need of most attention, that is, farthest from the goal are reducing cigarettes, reducing smokeless tobacco use, increasing actions of control on blood pressure and decreasing injury rates.

Finally, the women's rates of prenatal

care and alcohol and cigarette abstinence were very commendable. STD rates are higher than we might like to see. Women's rates for condom use were lower than those of men. Lots of issues I think could be talked about with the stress and coping. And the dental, which we just saw, was very high.

We think the big challenge is going to come down to these areas -- the heavy alcohol use, the tobacco use, and the hospitalization for injuries, at least as you compare those with the targets. One might argue maybe those aren't the best targets to use, but at least for the moment, those are the areas where the big gaps exist.

Finally, those who want to dig into this some more, there is a highlights report out there on the Tricare Website, where you can get more details than you ever wanted to know about this. I would be happy to work with any of you to help explore these data any more. One of the exciting things about this is there is lots of data here. One of the unfortunate things is that there is lots more analysis that needs to be done to really dig into and understand these things. But there just hasn't been funding to do that. So lots of opportunities with

this data set.

DR. PERROTTA: Thank you, Dr. Bray. Questions? Dr. Atkins?

DR. ATKINS: Was this a self-administered survey or an in-person survey? What was -- and I am wondering if that could affect some of your comparisons to the national data which are based on a different survey mechanism?

DR. BRAY: Very similar to the way the National Household Survey data were collected. We actually sent people to military installations and it was done much of -- kind of in a classroom setting where people came in. It was self-administered in the sense that they fill out the booklet. It was an in person interview for like the civilian data. So pretty comparable.

DR. SOKAS: Would you have access to the lost work day rate for the people who are self-reporting some of these activities so that you could compare self-reported stress and subsequent lost-work injuries or work time, that kind of an outcome cost of the self-reported stress?

DR. BRAY: No.

DR. SOKAS: Okay. So the information is

not linkable to that kind of information. But you would be able to do maybe injuries for the same -- are these self-reporting?

DR. BRAY: It is not linkable. It is self-reported, but it is an anonymous survey because of the drug use stuff and the implications of that. It has always been done anonymously.

DR. SOKAS: But the injury then is also self-reported?

DR. BRAY: Right.

DR. SOKAS: Okay.

DR. BRAY: That is one good challenge to injury data based on this.

DR. PERROTTA: There could be some linkages, but at very broad areas. Not on the individual level.

DR. BRAY: Right. Not on the individual level. You could look at subgroups, for example.

DR. PERROTTA: And that would add some verification or refutation of what the statistics said.

DR. SOKAS: Obviously we were trying to get at whether you could -- really looking at workplace stress, whether you could get out what is

the cost of that, but it doesn't sound like that is probable.

DR. REINGOLD: I actually have three questions. The first one is do you have any data on non-respondents? It seems to me that your response rate is less than 60 percent, so these data are suspect in terms of how representative they are of the rest of the population.

DR. BRAY: Do we have any data on what?

DR. REINGOLD: Non-respondents. Do you have a response rate under 60 percent or not? This certainly raises the question of whether the data are still as representative as they were when you had an 85 percent response rate.

DR. BRAY: We don't have them. Part of that is the problem that comes from doing this anonymous survey. That is a good point. The statisticians have done all of the normal things they can with non-response adjustments. In particular, where we have looked at some -- most of this was done in person, but some were mailed for people that were too far away and people that weren't available to attend the group sessions when we were there. We have done some adjustments with those people. One

might argue that if they didn't come when they could have come, are they more like non-respondents who might be more reluctant to participate. So we played around with some of those kind of things. But you are right, yes, there are still occasional biases that could exist.

DR. REINGOLD: Did the same function happen in terms of people overweight? Do you actually measure them or do you ask them their height and weight?

DR. BRAY: No. We asked them their height and weight and their age and then we created the BMI. So it is self-report on the height and weight.

DR. REINGOLD: Aren't there pretty good data that people tend to underreport their weight and overreport their height?

DR. BRAY: There is some data along that, but there is also some data that says it is not that bad.

DR. REINGOLD: I guess the last question is that I am sure that men and women in the military have sex with men and women who are not in the military, but don't the different reporting rates of

condom use suggest that men are perhaps optimistically overreporting their condom use?

DR. BRAY: I am having a little trouble hearing.

DR. REINGOLD: The discrepancy in the reported condom use. I am sure that people have sex with people outside of the military. But it suggests to me that men may be overreporting their condom use.

DR. BRAY: Why would you think that?

DR. REINGOLD: Because they are reporting much higher rates of condom use than the women are, and I guess a lot of time they are having sex with people in the military.

DR. BRAY: I guess I am not seeing why that -- why they would report differently who they had sex with.

DR. REINGOLD: Well, if the sexual encounters are between two people in the military, there would tend to be some correspondence between the reported condom use for that sexual act. The men and women are --

DR. BRAY: This isn't pairs that are reporting.

DR. REINGOLD: I understand that. But I

guess I am just questioning how good the data are for men about condom use.

DR. BRAY: Well, it is a question one can ask about any self-report data, which is always subject to potential biases.

DR. LAFORCE: Are there enough data for you to be able to show that there are fewer cigarettes sold? In other words, it is pretty impressive if you look at the decrease in tobacco utilization, and I was just thinking is there a way of confirming that on the basis of just pure economic analysis in terms of how many millions of cigarettes are actually sold in the military on posts or wherever. Or is that too arcane a question?

DR. BRAY: The question is a good one. These data don't get at any of that, and you are saying are there other data that could be looked at in terms of sales data.

DR. LAFORCE: Yes. I would think that is so impressive that there probably are just some raw economic data in terms of total number of cigarettes per individual, and that you ought to be able to show this pretty dramatically.

DR. PERROTTA: Dr. Baker?

DR. BRAY: Maybe someone has a little bit more information about that. It would be nice to do that analysis. I know they tried to -- there has been some analyses done that has tried to look at the cost of tobacco use in the military, but I don't know that they have looked just at the sales.

DR. BAKER: Susan Baker. I wondered whether the tremendously lower illicit drug use -- whether that might reflect greater concern about the confidentiality of the report or be related to the 59 percent response rate, or whether is there drug screening at the time of enlistment that would keep out the illegal drug users?

DR. BRAY: Well, my personal belief is it has to do with the effectiveness of the urinalysis test program. You know, you raise a good point. Are people going to report this knowing that it could have an impact on their military career. The only thing that we have been able to look at somewhat in terms of confirmatory data are the data on the urinalysis testing program, which aren't done as part of the survey or in any way connected with it. But those rates also show declines over time, which are -- one could say is there any kind of validation, and

that may come closest. It is still not perfect by any means.

DR. PERROTTA: Colonel Bradshaw, then Dr. Music and Major Smith -- Colonel Smith, I am sorry.

COLONEL BRADSHAW: I am not sure if this works, but I am pushing buttons. They are both up. At any rate, this is Colonel Bradshaw. I was trying to get at just the volume of cigarette sales. That might be difficult if you are only looking at the commissary sales. Because a lot of retirees come in and buy them by the bundle. They will fill up there -- because heretofore, we have had a significant price difference between what you can buy -- you could have bought tobacco at cost on base. Currently in one of our initiatives, we are trying to get that up towards comparability with at least what is in the local area. Because as we all know, if you increase the price of tobacco, the consumption goes down. So we are trying to get that through. But this is sort of an issue because our Morale, Welfare and Rec people use the profits off tobacco and alcohol to fund things like the Child Development Centers. So there is this push/pull sort of thing on that. But consumption would be confounded, I think, by the

number of retirees and other people that are eligible to buy cigarette use, and we don't have quite as much an impact I think on them.

To answer also one of the other questions, the HEAR, the Health Evaluation Assessment Review, is another self-reporting tool that we have where we can link stress by Social Security number with our other data bases looking at lost duty days and hospitalization and things like that. The problem there also there is we are having trouble getting the data back from this tool. The difference between that and this survey is it is not anonymous. But because it is not anonymous, we can link it by Social Security number. So that that would be another way to look at it and we can do comparisons.

Also on height and weight and body measurements, like in our Fit Management software in the Air Force, and I am sure there are similar things in the Navy and Army, we can compare BMI measurements and height weight percentages with Healthy People 2000 folks directly because we do directly measure those and keep that data.

DR. PERROTTA: Dr. Music?

DR. MUSIC: Did your statisticians

calculate confidence intervals so that you could know whether the comparisons that you displayed are in fact meaningful?

DR. BRAY: Yes. We calculated -- rather than confidence intervals, standard errors around each of these prevalence estimates so that we can look at the changes.

DR. MUSIC: Then all the ones that you displayed are meaningful -- statistically significantly different?

DR. BRAY: Well, let's see. I think you've got to say relative to something else. What are they compared to? But the trends, for example, are significant drops across time in the substances. I would say it is a fair thing to say what we are putting up there are meaningful kinds of numbers.

DR. PERROTTA: Let's take one more.

DR. WEINSTEIN: I have a couple of questions. Or at least one is a different spin on the results you told us about how people felt about seeking counseling and the possible effects on their careers. You mentioned that about half the people -- equal numbers felt that it would definitely hurt their career and the same number felt that it

definitely would not. There was that huge group that said may or may not. If you take the people who -- all those who said it might hurt their career, that was 80 percent of your total. So a little different spin on that.

DR. BRAY: And that may or may not mean -- it may mean they are nervous.

DR. WEINSTEIN: Yes, they are concerned.

DR. BRAY: Right.

DR. WEINSTEIN: Although I think this data are very valuable and you are doing the best you can. A point on one example, which should make us pause about self-reporting accuracy, on the testicular self-examination, there were very high numbers claiming to do an exam every month, and it seemed to me that about two-thirds of those who said that they had ever received instruction. So now supposedly following the recommendation, they are doing a monthly self-examination, which is certainly not true. So at least for some of these behaviors, there may be a lot of over-reporting of desirable behaviors.

DR. BRAY: That is very possible too.

COLONEL BRADSHAW: Just one other quick

comment. I can resolve partially at least for one population this cigar versus pipe use. We did a chart review and some data on the HEAR survey and so on among some senior officers, and it was almost all cigar use for other than cigarette smoking. There was no pipe use.

DR. PERROTTA: Okay. Let's close with Dr. Atkins.

DR. ATKINS: I think you already alluded to this point, but certainly Healthy People goals based on the U.S. population demographics wouldn't be appropriate for the military demographics. I assume you didn't adjust for those. Like the injury is the obvious example where that, from what we heard before it may just reflect the younger demographics in the military and the higher injury rate in young people.

DR. BRAY: That is correct. And in fact, if the military would really get more involved and into Healthy People, they in fact might want to set their own objectives that say some of these civilian rates don't make much sense. They are not for us. For some reason this 20 percent goal for smoking is a real military goal, and I have no idea where that came from. That is different than the civilian goal

for smoking. So somewhere along the line, somebody has done a little thinking about that. But I don't think uniformly across this.

DR. PERROTTA: Okay. Good discussion. Thank you very much. Colonel Rich Dennis is from the Office of Army Surgeon General, and we will close the morning out with a DoD Information Management for Preventive Medicine and Occupational Health discussion.

COLONEL DINIEGA: Beth Collins was going to be speaking on Put Prevention Into Practice for DoD, and she had to go off to Germany and I haven't heard back from her. I think she was getting back last night or today sometime. So we will put her on the agenda for next time.

COLONEL DENNIS: While she is getting that ready, I will tell you that this is a DAR brief. If you don't have a top secret clearance or if you are a foreign national officer, you have to leave the room. Andrew, that gives you your chance to get out early.

It is always kind of dangerous working with an audience this close. I feel a little more comfortable with a podium this size. I am going to

talk to you very briefly and paint the IMIT efforts at DoD Health Affairs with a very broad brush. I will mention some of the key elements of some of the four programs that I am most intimate with. Any questions you have, I will be happy to answer. I know you are -- I see a lot of heads nodding out there. Joel is getting kind of old. It is tough for him to keep upright anywhere. So we will try and get through this as quickly as we can.

These are the four systems that I am most familiar with and that I have worked with and I have had some functional interaction with. I'll also mention at the end of this the CEIS, which is the Corporate Executive Information System, which has some impact on the way we will do business in the future and will be designed to interact with the system we are going to look at now.

CHCS II was designed to be the computerized patient record. That is where all of the healthcare data will repose in the future. We hope that is the case. It is going to be the MHS, the Military Health Systems automated system. It will be the system for all of the Services. There is always some contention about what should be in there.

Many of you have had a chance to experiment with these and have been the clinicians involved in looking at the functional requirements. Much of the work that you have done has helped us change what we are doing and how we are designing new systems.

Now I want to emphasize too that I am on the functional side of this and not the technical side, so I don't have solutions for all the problems that you find. That is up to somebody else.

The thing that is coming in the near future is the personal information carrier or personal identification carrier. It is supposed to take the place of the dog tag. There has been some contentiousness over the last year and a half or so over exactly what mechanism we will use to determine how we carry information on the individual relative to his demographics and his health status. There is a mandate that this personal information carrier be tested by the end of December of this year. I don't know exactly what form it will take. It is likely not going to be the end-all, but there are some -- there has been so much money thrown at this program, and the Joint Staff is very interested in seeing that we get something out before the end of this calendar

year.

The CHCS II was designed to be compatible with the theater information program. Pardon my use of acronyms for those of you who weren't familiar with all of these. The theater information program is the program that will carry all the information on any of our deployed Service members and any of the information gathered from those deployed Service members while they are in the theater.

PHCA, you've heard some mention of this before, the Preventive Health Care Application. It is apparently going to be trimmed down because of some problems it had with the note writer that they had originally chose to go with the CHCS II package. But its basic components are as you see them here, immunization tracking being the most important for many people. Anthrax is a big issue for the military right now. We are immunizing all over the world against that potential problem.

The PPIV, that you heard spoken about before, is pretty much in the clinical preventive services. You heard David talk about the HEAR self-assessment tool. This system is now deployed or in the final stages of deployment for 60 different posts

here in the United States. It will be stand alone for probably quite some time. There has been some problem with the note writer chosen for the CHCS II, which is the mother ship, versus what PHCA was developed for, which was something entirely different.

There is a pre and post-deployment questionnaire. Some of you here I believe helped develop that questionnaire early on. It is designed to ask some very specific questions, none of which come to mind right now, before they go and right after they go to determine if they have been exposed or has there been any intervention during the period of time that they have spent in theater.

In addressing the occupational health portion of the information management and information technology, the DOHRS system has been developed. It is essential. It was developed because of these issues, but it has an industrial hygiene, hearing conservation, occupational medicine module. The most mature at this point is the hearing conservation module. I think it has been deployed -- Paul, you could help me with that -- to 2,000 places or will be in 2,000 places, including National Guard and Reserve

Units throughout the United States Air Force. Everybody is going to have it. The one that is under construction right now is the industrial hygiene module. The templates are being written out in Hawaii. There has been some experimentation with that. It seems to be going well. The timeline for that is sometime between June and August of 2000 to have that at its mature point and have it ready for deployment.

The occupational medicine module is the weakest of the three, and those of you who have used OMUS in the past recognize the drawbacks. The upgrades through the occupational medicine module are designed specifically to address those difficulties that we had with OMUS, which was the Army Occupational System several years ago. And this is what these modules will essentially do for us.

I know you want to read those slides to you. The team that is essentially going to be the medical command and control where the trigger pullers have their command and control system, this would be ours, and this will integrate with theirs. This is designed to be a system that integrates with all the command and control capabilities that are available

to a theater commander, so the commander in chief in the theater. And block one is now being deployed. These are the elements that you will see in block one. It will carry the patient demographic data to these other systems that you see there.

And of course one of the important things of documented health data, those of you who have been involved in evaluating the Persian Gulf illness and all of the attendant problems that came with that, the mandate from the Congress and the President was don't let that happen again. Let's have a system that will allow us to identify what happened, where it happened, who was involved and what the consequence of that involvement was. This, we hope, will go in some measure to help us evaluate all those things.

Okay, was that quick enough? Can I answer any questions?

DR. PERROTTA: Any questions for Colonel Dennis?

COLONEL DENNIS: Anybody that has an extra $8 million or $12 million dollars that they can blow on Health Affairs to help with the continuation of development in any of these programs would be

greatly appreciated. Thank you.

DR. PERROTTA: Is there a question in the back?

DR. BRAY: When do they expect this automated system to be usable?

COLONEL DENNIS: Three years ago. That seems to change almost all the time. And actually I wasn't kidding when I -- there is a significant deficit. The DoD Health Affairs and the IMIT budget is about $1.3 billion dollars short. The Surgeon General argued successfully to get some of that back, but there is still a significant deficit. So it has not been decided yet which of the systems will suffer most greatly from not having enough money, but due to reorganization of the business area, which is the controlling interest here in the CHCS II, which is basically the mother ship -- and I had an opportunity to talk with Admiral Fisher, who is the executive agent for CHCS II development at the 4th Health Profession Conference in Atlanta, and he told me that they were about an inch and a half away from telling the joint review people to ax it and just go on and develop it themselves.

PARTICIPANT: The PHCA does not integrate

with CHCS. Do we anticipate that there will be problems fully implementing PHCA due to the fact that it is not integrating and have to bring up two things on one screen?

COLONEL DENNIS: It looks like they are going to lose the HEAR and it looks like they are going to lose the immunization tracking module from PHCA, and that has a direct significance because of the change in the operating systems from conformance with Oracle. They were developed in two different systems. In fact, there has been a significant change now. The CHCS II -- again, the mother data repository -- was developed in McCormicks and THIP, which is going to be the actual theater application, which will be the most important, was developed in Oracle. They had to make a change. Some of the systems that were being developed to match up with the fund and business area can't do that now. I can't predict in the future exactly how that will work out, but I suspect it is going to be a problem. Joel?

COLONEL BRADSHAW: This is Colonel Bradshaw. I just wanted to clarify a couple of things. The current PHCA module or system is being

put into 60 different NTS across DoD. It integrates with CHCS I, the original one. So it draws data, particularly laboratory data, and it functions as a reminder system for clinical preventive services. It also has a module for immunizations, the RMS module, and it also has one for HEAR. But you should still be able to use where it is being deployed the clinical preventive services reminder system, and that will pull data. It won't push data, but it will pull data out of CHCS I. CHCS II, the approach that is being taken, is that the functionality of PHCA will be integrated within CHCS II using CHCS II architecture. They are currently using a 3M product that Intermountain Health Care, a large HMO out in the West, is already using. So we are adapting that for our DoD computerized patient record. So what several of us that are the functionals that you mentioned are doing is making sure that the current functionality that we have in PHCA will be integrated -- it will be part of CHCS II.

PARTICIPANT: What is PR85?

COLONEL DENNIS: It is the presidential -- R directive. It says that we will no longer deploy forces without giving them some kind protection. I

mean, that is the broad brushing paint set.

DR. LAFORCE: Is CHCS II -- will that be able to be read by the VA Health Care System?

COLONEL DENNIS: I don't know whether that -- the plan -- the long range plan is that there will be integrated data bases between the VA and the active military. And that is because now we have almost become a single health care service. But the plan of the future is -- now it won't do that now. They are planning those issues echelons above where I work. But I think that is the ultimate goal that they will be able to talk with each other and share that data. In fact, this whole data base at some point is supposed to become web enabled. If one of us were in theater and we needed information that was gotten on an individual back at Madigan Army Medical Center, we would be able to query that information. We are trying to work those security issues as we speak.

DR. PERROTTA: Let's close.

COLONEL BRADSHAW: Very quickly. There is a separate initiative called the Government Computerized Patient Record, GCPR, that is looking at integrating the VA, DoD and other ADL systems.

DR. PERROTTA: Okay. Let's take 60 minutes for lunch. It is about 1:15. We are doing fine on time. We are closing a little early this afternoon, so we have some back-end time. 60 minutes.

(Whereupon, at 12:15 p.m. the meeting adjourned for lunch to reconvene this same day at 1:18 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:18 P.M.)

DR. PERROTTA: Lieutenant Colonel Paul Smith will be presenting. I got it right that time, rank and name. It's hard, especially for a guy from Texas, East Texas.

LIEUTENANT COLONEL SMITH: Are these mikes working? Good afternoon. This is Lieutenant Colonel Paul Smith. I'm from the U.S. Army Center for Health Promotion Preventive Medicine. Currently I'm director of preventive medicine.

It's a pleasure to talk to you today about a problem we encountered in Europe in a particular building, whose number I'll we'll all probably remember forever, building 4109 in Pirmasens, Germany.

This is a very quick reminder about what heavy metals are. I think that sometimes we forget to go back to basics. Here's 2A through 6A of the periodic table, which I have a copy of. There are several known sources of heavy metals. They're well known; they've been known for many years. Heavy metals have been mentioned as far back as Egypt when they used lead alloys to make some of your statues.

In the Middle Ages, Agricola and Paracelsus talked about the heavy metals and correct me if I'm wrong, Dr. Sokas.

Some sources of heavy metals are mining industries, foundries, smelters, plating operations. We also get it in metal piping, and sometimes from the lead, and I think that's well known, in pipes. And as by-products of combustion products, leaded gasoline, at times welders, when they're welding, will get combustion. Volatile heavy metals are fit for very, very wide displacement. Also organically bound heavy metals are much more toxic.

This is just some of the very general effects of heavy metals. Primarily you get pulmonary effects. Some of the heavy metals are carcinogens or thought to be carcinogens. Renal effects including renal failure, and at times renal cancers. And then effects on both the central nervous system and peripheral nervous system depending on the metal. Some of them have -- this is a history of building 4109 in Pirmasens, Germany. This was a former COMMEL. COMMEL means communications and electronics maintenance shop. It was used from the 1950s to about 1994. Some of the industrial processes in this

building were electroplating. This included heavy metals, cadmium, copper, nickel, chromium. They did diptank cleaning, they did abrasive blasting, surface sanding of metals and tanks, welding and cutting, and there was an extensive machine shop in this building.

In 1992 this building, actually 1990, was slated to be closed and demolished. And in our downsizings we lost the money to demolish the building. The building was really subsequently occupied in '92 by the 226th Medical Logistics Battalion and the U.S. Army Medical Materiel Command Europe. They accepted total responsibility for this building in about 1994. The history of this building eventually was lost industrial.

Some of the activities, what I'll term as USAMMCE/226th did inside of this building were they used it for office space. Because it is so rainy and cold in Germany they did a lot of unit PT in inclement weather. They had formations. They did unit training inside of this building. They did some unit social functions. And there were warehouse activities done in the building including storage and a lot of forklifts.

This is a picture of building 4109 in

Pirmasens. This picture actually does not totally do justice to its size. It's about twice the size of what you're seeing in the picture. It's a huge building and all these roofs are actually one building. It's one building inside. It's about, by American standards, probably two blocks by one, one and a half blocks width in length.

This is a layout of the inside of the building. The red area actually when we started to sample was the most contaminated area in that building. The blue, the little blue squares in there are actually diptanks where they did diptanks and processing. The green areas were virtually clean. And the yellow areas were somewhat noxious.

One of the worries that I had was the bleacher area. That's right here, because the bleacher was so proximate to the area in red. However, that area that was in red was supposed to be totally closed off during any time they occupied the building. Once we investigated, we found out that that was not the case because people had stored furniture within this bay, now turned into storage area.

This is a picture of that storage area

when it was in operation, or just after it went out of operation. And if you notice you can see the scaling on the tanks, and in fact you can see the industrial hygiene attempts to regulate some of that, the noxious fumes coming off of the tanks. This was heavily contaminated with heavy metals.

This particular history truly has been lost, that this had been used as a maintenance facility in which they ground metals, and they ground some of these down to cadmium and chromium. Incidentally, something that I found a little disturbing myself, I believe these are German nationals back in the early '80s when this was taken and we see a lot of them protecting themselves, at least by American standards now.

In June 1998 the area which we called "shop" was sampled. The reason that this happened was some of the personnel spotted some small little signs that had chromium and cadmium on them. The industrial hygienists then sampled that area and those samples were received back in about September of '98. It takes a while down here to get these samples processed. At that time we informed 415th and USAMMCE and then restricted personnel from the

plating area. It was felt that at that time it was likely that the areas of the, you know, areas where the office was at and certainly the area that had been converted to office would not be contaminated.

In November of '98 there was an entire environmental sampling done in this particular building. These were received back in January of '99 and the 415th and the USAMMCE commanders were then once again briefed and building access was restricted to the office space only when we found that the contamination was out in the warehouse area too.

This is some of the representative numbers from those environmental samples when the entire building was sampled. We tried to go by the strictest standards, and the German standards are much more strict than our own. These were remedial standards, these are EPA type remedial standards from something that's called, commonly known there as the ALEX list. You can read them for yourselves. Cadmium was 20, chromium was 600, and lead 1,000. Our highest number found in the whole industrial area was 24,000, chromium was 2,000, and lead was 5,800. The warehouse was a bit better. The highest number was 490 cadmium, chromium 740, and lead 4,100. And

this is milligrams of metal per kilogram of dust.

When it was discovered that those metals were there the occupational medicine physician at USAMMCE in Europe ordered lab tests on a representative sample of those people. And he became concerned when he saw elevated ZPPs and Beta-2 microgobulin. ZPPs are indicative of a prior heavy metal exposure within the last three months or so. Beta-2 microglobulins are used to monitor people for cadmium exposure,they're used as a monitor in occupational settings. The good part of this was the blood lead, cadmiums, urine leads and urine cadmiums all came back normal in these people.

Once those were order, a second group was tested, which once again show 47 elevations in ZPP, and five elevations in Beta-2 microglobulin, and still there was no blood cadmium, blood lead cadmium or urine lead elevations. One must bear in mind that as the time passed, the chance of finding a blood lead or blood cadmium went down. We developed an evaluation sequence for these workers, soldiers at Pirmasens. This included the screening laboratories, some of which you've just seen, a medical and occupational history, full physical examinations for

those that were potentially exposed, and a medical opinion and follow-up examinations for any individual that had metal.

The medical protocol we developed included a pre-printed SF 600, and in fact we borrowed some of the Navy's PC matrix, which was considerably lighter. We did screening labs of the ZPP, Beta-2 Microglobulin, lead and chromium levels for recently exposed people because we knew we might pick up something on those. For people who were a little more distantly exposed, I'm talking about 1,000 in about three months, three, four months. We did a urine and beta-2 microglobulin. These physical exams were then reported on pre-printed SF 600. And we especially insisted that the provider concentrate on the nervous and renal systems because those are the main target organs that we thought would be affected by these metals.

We did develop an exposure assessment, at least what we felt was a surrogate exposure assessment for the soldiers and the workers that were there in that building. We tried to get he average number of hours per day that they spent in the building, and the days per month that they spent in

the building to get a surrogate measure of potential exposure. We asked them the types of activities, did they do PT, did they work, did they eat, particularly in the facility because of getting heavy metals on their hands and eating it. We asked them about lying and sitting on the floor since they did physical training in there. And I guess anyone in the Army during training does a lot of situps.

And we also checked for some of the confounders such as well water, asked them if they were hunters, if they were shooters, things that would expose them to lead, reloading ammunition, stained glass work, handling chemicals that they might have used in their hobbies and home.

I'm not sure just how well this will show. This is a three part appended form that we sent out to the providers to get these histories, and basically what you have on there is the room name. Then they have a map of the building, the activity that the person did during the time that they were there, and their best estimate of the times that they were there. This was something that's certainly not scientific in how it was reported.

We then arranged for follow-up exams as

we felt they were implicated, and provided they were indicated, especially asking about neurology, nephrology evaluations, and then lumping all the others as "others." We had in Germany about five, I believe, follow-ups, all of which came back normal. Some people had some problems which were apparently not related to exposure. In about 300 that we've examined so far we haven't found any abnormalities at all.

This story broke to the U.S. Army Europe Commander in April. The two-star commander then decided that we identify all the soldiers who had PCSd and ETSd. That's where I became involved. Up until that time, it was the occupational medicine physician in Europe. He also announced this openly in the Starts and Stripes, and CHPPM-EUR and Landstukl Regional Medical Centers started to evaluate more than potentially exposed personnel in Europe and arranged to follow up with local nationals.

There had been greater than 400 soldiers that PCSd or ETSd of approximately 700 total soldiers who had been involved in this building who were found. We developed and distributed information to

all the soldiers that we could find. We developed provider guidance to disseminate to our field, developed letter of instructions to the regional medical commanders, preventive medicine services in the Army, and the occupational medicine services as well.

We were charged to develop and maintain a database at CHPPM. I called it an exposure database, although the actual charge was simply to put their names into a database so that they could retrieve it. And additionally we developed soldier notification letters which we sent to the soldiers.

Some of the things that we did to try to disseminate information were provide a soldier and family information web page which is on our CHPPM home page listed. We developed a web page for provider guidance. It has all of the 600 forms. It has information specific to train the providers in how to look at these patients.

About the web page, I guess it's on a secure server. It does get to the providers. And we established an e-mail address which it can read in which providers can tell us when they see a patient and that keys us to start following that to make sure

it overlaps. We set up a system in the States where the preferred route of routing soldiers was through occupational health clinics because we felt like occupational medicine physicians and nurses were much more adept at dealing with the potential exposures which are dealt with as an occupational exposure relatively quickly. As an alternate we provided a route through the PM services. For a few family members that asked to be seen, and there's been very few so far, we asked that they be routed through the primary care provider, that the forms be routed back through occupational medicine and preventive medicine so that we can collect that information and store it in the database at CHPPM.

This, too, may be a bit difficult to read. The important numbers there are your U.S. values and your German values, or some German values. The U.S. values for cadmium, which is an industrial remedial and that means not where a child is going to live, is 930 milligrams per kilogram. And chromium was 450 milligrams per kilogram. There is truly no established reference level. So what's become the accepted-level basically worldwide is 1,000 milligrams per kilogram, and that's the one that we

used.

This once again is showing the levels, some of the levels found in the building at Pirmasens. And here they raised some numbers -- 24,000 milligram per kilogram cadmium level in the shop -- and when we did a total risk assessment, an EPA-type risk assessment. Most of the risk stems from that 24,000 milligram area. One of the problems involved was we can't for certain know how many people we had in that area until we questioned them.

There were some limitations of the risk assessment that were inherent in developing, in how this scenario developed. We had a limited number of samples. Part of the reason the number would remain limited is once the commander of Europe found that this building was contaminated, he sealed the building and removed all the personnel from it and sealed the building. And I think that was probably wise on his part. The nature of the samples obtained were bulk dust samples. These are environmental type samples.

Unfortunately these people, some of these people were in there for a considerable period, so they really fall into gray zone -- were they

environmentally exposed versus were they occupationally exposed -- and we had no occupational breathing zone samples of people that worked together, so we had to extrapolate from the environmental sample and apply it, plus occupationally test, too.

One of the other problems that I see as a limitation in the risk assessment that we did was it is a one snapshot in time. So we collected those samples and got the numbers back, but we certainly can't apply that qualifying exposure on a previous basis. And what I mean by that is if a person was there in 1992 and we collected the samples in '99, we cannot assure ourselves exactly what those numbers would have been five years earlier. We could use the models, things of that nature, but I haven't talked to any of these patients myself. I'm quite aware that they swept the area up many times and it's hard to tell exactly what that number would have been four or five years later.

There are some pending issues. All these people are now working. Separated soldiers and family members were a problem; they no longer are. I did get Secretary of the Army designation to be

seen for this problem.

Long-term follow-up. Army Reserves. We have worked on identifying and examining any Army Reserve where they're at, and that's being done, as I speak. We are arranging for travel costs for patients from remote locations such that, if they have to travel long distances, we can reimburse them.

I have worked with the Navy Commander. There were Navy personnel involved in this building. They used it for preparing for humanitarian relief missions at times. Apparently there were very few, if any, Air Force personnel in the building. And obviously finalizing my database is still pending.

There are a few lessons that I feel I learned from this incident. One is vague risk evaluation and risk communication. And from that I mean I think we could have better explained to our line commanders the true risk of this building. When we finally got a chance to do a full EPA-type risk assessment on the risk, we found the risk to be very, very small. However, because that risk wasn't truly quantified at the time that this commander felt obligated to release this information, he felt he didn't know what kind of risk they had, and I think

we could've better communicated that, too.

Another thing is environmental versus occupational sampling. To attempt to use environmental dust samples and extrapolate them to occupational breathing zone samples is tenuous at best.

Some of the screening laboratory limitations. Beta-2-microglobulins can be confounded by disease processes, like diabetes. Actually I believe you exercise that even before you collect an elevation. ZPP. Anything that affects protoporphyrin will change ZPP. Sometimes when a lady is menstruating, that will.

One of the other things is the relationship of the line and the medical. I think I've already alluded to that in the risk communication, that we can learn to better communicate with our line commanders. And the other little saying I have there I think goes without saying. Question everything. Accept little to nothing at face value.

Yes, Dr. Sokas?

DR. SOKAS: I had a question about the actual levels of the blood leads that you saw. When

you say "normal," that can cover a whole range. Did you have a sense of where in the range that fell?

LIEUTENANT COLONEL SMITH: Yes. I will give you the most, the largest one that I have seen was unequivocally an exposure to lead. It was 490.

DR. SOKAS: I'm sorry?

LIEUTENANT COLONEL SMITH: That one happened to be 490.

DR. SOKAS: No. The blood levels that had been taken of people.

LIEUTENANT COLONEL SMITH: I'm sorry. Go ahead.

DR. SOKAS: What were the blood lead levels from the people who had blood lead levels taken that were reported back as normal?

LIEUTENANT COLONEL SMITH: We only used the lab normals from -- we sent them all to the same lab. I don't know exactly just how --

DR. SOKAS: Okay, but --

LIEUTENANT COLONEL SMITH: -- far within normal range they were. Some of the ZPPs that were elevated could have in fact been in elevated blood lead levels earlier. However, when these were first drawn, these people were still in the building and

still under the same potential exposure scenario, so one would have thought that their blood lead would even have been out of the normal range.

DR. SOKAS: Yes. I apologize. I may have to run. I just wanted to make one little point, that the ZPPs, as you've mentioned, can be upped with iron deficiency, and the beta microglobulins are also non-specific.

The blood lead levels actually, if you got to plot the actual numbers, there is a huge range, and the lead blood levels predict about 50 percent of total body stores. So the difference between the average person walking around in the United States now, which is less than three. And we all grew up -- I mean those of us, you know, who remember the Honeymooners -- all grew up with levels around 16 or 17, so that's kind of the range that we've been coming down as a society. So you can get a huge amount of information if you've got a large enough population size. On, you know, a population of United States citizens who are now at 20 versus what you'd expect which would be three versus maybe eight or nine, which you wouldn't worry about so much.

LIEUTENANT COLONEL SMITH: Yes.

DR. SOKAS: So you can get probably more information out of the leads than out of anything else you're going to find there, certainly cadmiums or urine or anything else.

LIEUTENANT COLONEL SMITH: Right. One of the problems that exists, too, is when you speak of applying the American blood lead level norms to people in Europe there's a considerable number there that still uses --

DR. SOKAS: Leaded gas.

LIEUTENANT COLONEL SMITH: -- leaded gas. So to be in a normal range by American standards and be in Europe, I think spoke very loudly.

This is simply my summary of soldiers who have been exposed. Family members were potentially exposed, although we don't think that there is a great danger of that. We attempted to provide the medical evaluations as well as we can, and we're going to consolidate that information into databases.

I've already had some question.

DR. PERROTTA: Any further questions? Dr. Anderson.

DR. ANDERSON: Yes. I think it would be

-- I'll just underscore what Rosie said -- to look at what the blood leads were. The other thing that can be done is to repeat the samples and see whether the levels are going down.

I guess to think about it in the future, would be to say, if in fact you don't know what normal is, to think in terms of doing a controlled population.

The other question would be probably screen more people than actually were exposed. Would you see any dose response relationship even if the lab considered it in the normal range. I think the critical factor there is what were they reporting as normal if they were using an occupational standard versus what they typically see in a population --

LIEUTENANT COLONEL SMITH: Well, what we considered this as, since the soldiers frankly were for the most part using it for PT in the morning, is the fact that it should be applied in an occupational standard, that's one that we went through the occupational screening with the soldiers.

Now for the family members, that's a different story. However, the family members were not in there every day, day after day. They did do

some social activities in that building. They had some Christmas parties, things of that nature. So even though we had environmental samples, it applied occupational standards once we started and so forth --

DR. ANDERSON: Yes. I'm just saying that if you were applying a level of 50, which is at least in the U.S. is where you'd remove somebody, and therefore you'd call it normal if it's below that when in fact the population is between three and ten, you may have been able to see them. I'm surprised to see the elevated ZPP depending on how elevated. And I think that further analysis of the work might show that.

LIEUTENANT COLONEL SMITH: Yes. With some ZPPs that are called elevated, we were very liberal. If it was one above their stated lab norm, we called it, they called it elevated.

I did consider asking to get comparisons groups within this exposure, but actually we sort of felt like within Europe, especially with the use of leaded gasoline, that it might not be really appropriate to maintain a control group.

DR. ANDERSON: Well, was this German nationals that you were studying or were they U.S.

servicemen? Because if they were U.S. servicemen who would rotate through, your comparison group could be other people at the same base who were there the same amount of time. I could see the difference between looking at a German national who was born and raised there versus a U.S. I guess my only question is you're kind of left with a difficult situation to interpret your data unless you have something to compare to. With just using the lab norm, you really need to know what those levels are.

LIEUTENANT COLONEL SMITH: Yes. Like I said, I did offer to develop a comparison study and --

DR. ANDERSON: What's happened to the building?

LIEUTENANT COLONEL SMITH: -- to interpret it as well.

DR. ANDERSON: So what's happened to the building?

LIEUTENANT COLONEL SMITH: The building is to be, is condemned. It is to be demolished or vacated. The standards are below industrial standards. One of the things that this did positively produce was an entire review of all the

buildings within our European field because they have had uses whose history was lost. And I think this possibly had a positive impact in that respect that we're now in the process of checking all those buildings and all the histories to make sure that there is not another building sitting there that's exactly the same or similar.

DR. ANDERSON: Do you know where the materials were disposed of? In your pictures there, there would have been a lot of metal sludge and whatever that might well be in a hole in the ground very nearby.

LIEUTENANT COLONEL SMITH: I'll be right up front with you; I have no inkling. Now I can tell you that it's obvious when there was sampling done outside of the building on the periphery and people had swept it out into the ground there in certain locations, that's how we had a sense. But we don't know exactly what that level was several years back because it was on the ground, obviously, in places where it had been swept out or taken out on tires.

DR. PERROTTA: Any other questions?

Yes, Mark.

DR. LaFORCE: I just want to make

absolutely sure that there was no clinical disease that you were able to identify despite what could have been a rather significant exposure.

LIEUTENANT COLONEL SMITH: Thus far, that's correct.

DR. LaFORCE: Okay.

LIEUTENANT COLONEL SMITH: Now, I'll be honest with you. I've not put our entire -- it's much too difficult for me to put the entire risk assessment, and I tried to give the limitations of that one risk assessment. I can't -- when you try to extrapolate that back in time, it becomes almost impossible no matter what model you're using.

The levels that we got, except for in the shop area, are in fact levels which you can go out in certain areas of the United States, pick up dirt, and find it there at the same level. So it reduced my worry level because my assumption is -- it's probably correct -- that not the entire unit went into the area to store furniture, probably only a few people. But I'm still left with the fact that I can't predict what the exposure was. I can't really say five years in the force that leads to examine. The company party is at 300 right now; 300 are normal.

There are another 400 at least.

DR. PERROTTA: Okay. Thank you, Colonel.

We'll continue with the CHPPPM afternoon and have another visit from Mr. John Resta. John is a frequent visitor to the board, and I appreciate you coming in and keeping us updated on a topic that I know the environmental and occupational health committee has been interested in as an adjunct to medical surveillance. Well, I won't steal your thunder, how's that, to talk about the joint environmental surveillance group update.

MR. RESTA: And what I will do with this, I'll yell into one of these mikes, go over a little bit of the background. For those of you have probably seen some of that two or three times, I apologize. But mostly I want to show you in regards to that what improvements and where we are making progress. Mostly to show where we've made some progress, so you'll probably see some stuff that you've seen before time and time again, but hopefully you'll see a little bit of new stuff on some of our retrospective work.

I'll talk a little bit about the directive instruction that we're building towards,

mostly the groundwork, and why we're doing what we're doing. Again, a little bit about the Joint Environmental Surveillance Support Group, it's current activities, and where we see it going in the future.

Obviously the basis for a lot of things that we've been doing are based upon -- I show these pictures a lot of times to people who don't think they know about them, mostly in an abstract view. They don't know about them in terms of the reality. If you can see, this sucker, this is an individual right here. That's actually Dr. Jack Heller, who is on our team, and that's how close people were to a lot of these things.

So to give you a feel for that and why these things actually changed a lot of the reasons we do what we do, again we have shared this in the past. Mostly I do this to show you the dataset that we have because I want to talk about how we're using this dataset for other things in the past.

For those of you who are not aware of it, we deployed people in May of 1991. We were there through December of 1991. It depends on how we count on tender for locations. We had in excess of 4,000

samples. From that, what we did is we modeled this using our friends at the National Oceanic Atmospheric Administration. When we started this model this was Hisplit. We are now on Hisplit version 4.0. And so we continue to upgrade this model annually in terms of source term estimations, better meteorological datasets and the like. We continue then to merge that with satellite imagery that we have that has been digitized.

Initially, what we did was we digitized this manually. We are in the process now, but when we did it, that's how you had to do it. Now, there is technology that we are starting to look at where we're going to try and digitize this electronically, where we essentially feed these digital images into a computer and have the computer recognize the out of bounds of the plume. Because that's important for us because then what we do is we merge the model plume with the satellite plume, add a buffer to make sure that we have a very conservative estimate of where we think the plume was, and then we can have a conservative estimate of the exposure. So hopefully within a year I'll be able to come back and show you the results of that, you know, that we've used

whatever, a Cray Super Computer and the like, and we've got better validity of our model.

Probably the things where we have made some of the biggest improvements in this effort has been troop locations. We have been working actively, energized by the Office of the Special Assistant for Gulf War illness, but actively what was U.S. Army and Joint Environmental Support Group but is now the Joint Center for the Research of Unit Records in terms of unit locations. We feel at this point that we are probably at greater than 90 percent accuracy at the tie-in level. Probably greater than 80 percent accuracy at the separate company level for maneuverable brigades for the combat units.

We still have great difficulty with specialized units, particularly Army medical units. Army medical units were task organized with everybody, and so if you try and actually look at a unit history of an Army medical unit, they changed flags probably a dozen times in the first three months of the operation. As the build-up came, their command and control changed and so it's somewhat difficult for us, particularly because of our alliance on PROFIS fillers in terms of either

Reservists who were active duty components that went to these units. That, however, represents a fairly small subset of the total people in there.

This is a representation of the headquarters, headquarters company for the 82nd Airborne Division. I don't know if I'm so close that you can see it in the back or what, but there's August 9th 1990 through December 31st. We actually have it for every month, and you can see that they enter here at Khobar Towers in August, and then essentially over the next three months they made a move. This is basically December to January 31st. They had separate movements, and here is one of the problems, it sort of washed out down here. The headquarters and headquarters company split. So we have dual records for the same unit identification probe. Some of them went down here to Prince Sultan Air Base, some of them went up towards Khalid Military City. There we go, that's through February 28th.

The ground campaign started. We start the end around and we end up in actually the Khamisiyah area of southern Iraq. At that point the ground war ends. And then we start to retrograde

down through here. We are here as of March 31st. And then we're down through April 9th, and that's essentially when the unit returned back to the United States.

We're using tools like this to again look at all of our files. We're also starting to use those tools for other things. Obviously some of the things we continue to do are still risk. This is currently a risk table for exposure to basically oil well fire smoke, a subset of chemical contaminates. What we have down here are units, days exposed. We have the maximum model carcinogenic risk, the minimum model carcinogenic risk, the maximum model hazard indices, an index of non-carcinogenic risk, and the minimum non carcinogenic risk.

What you can see here just for the sake of discussion is that we're looking in terms of carcinogenicity of oil well fire smoke in the ten to the minus ten range. For those of you who are unaware, EPA point of departure is 10 to the minus six, so we are four, at least four orders of magnitude below their level right now. So oil well fire smoke, limited set of contaminates, so we're not, this is not all environmental contaminates. We

continue to work on things like particulates, completed uranium, pesticides, and various other exposures.

One of those exposures obviously was this at Khamisiyah where, if you're not familiar again, March 4th and March 10th units of the 82nd Airborne Division, the 37th Engineering Company made a donation. Bunker 73 was March 4th. This pin here was March 10th. We had 122 millimeter rockets. It subsequently turned out in the United Nations Special Commission on Weapons of Mass Destruction that they were filled with sarin and cyclosarin, a nerve agent. And since that time we have been involved, with the Office of Special Assistant Gulf War Illness and various other players, in trying to map what the exposure might have been.

To give you a feel for some of the efforts in that regard, we have, let's see, lot of plumes. We're in the process of redoing these plumes as we speak. They should be published shortly, and so people will say what's happening. And again we are sitting here taking improvements in the unit location database, we're talking improvements in the meteorological datasets used for these things in

terms of which way was the wind blowing, how fast was it blowing, taking a look at that. And we're also trying to treat the source codes.

DR. PERROTTA: Could you explain the epidemiological footprint?

MR. RESTA: Yes. The first set of plumes that we did is an ensemble of models. And down here you'll see that we took essentially three different dispersion models, combined it with two different meteorological datasets,and then put it all together and then drew the out-of-bounders. And that was chosen as a conservative approach such that we could notify the individuals in here. We didn't think that that really was the best answer. For a policy decision it was very conservative, but for scientific study it was not.

So then what we did was we took SCIPUFF, which is a dispersion model. The proponent now is the Defense Threat Reduction Agency, which used to be the Defense Special Weapons Agency, and COAMPS, which is a meteorological dataset, combined them and felt that that was probably the most accurate scientifically defensible representation of the situation. And from there we're using that to

identify people who we would want to do an epidemiological study on. And Captain Gray is here somewhere -- I saw him earlier -- and is actually deeply involved in that regard. And so the results of that should be coming out.

Here are some publications that have come out. Again these are mostly Captain Gray's work; we just help. One, risk factors with respect to mental disorder hospitalization after the Persian Gulf War is in the *Journal of Clinical Epidemiology*, and then the post- war hospitalization experience among Gulf War veterans possibly exposed to chemical munitions destruction at Khamisiyah, *American Journal of Epidemiology*. So they're out in the literature now, and they have been received somewhat positively.

Switching gears to try and give you an update of where we are with Bosnia. Again to try and give you a sense of why we're concerned about this, this is Camp Poxetani in Lukavac in Tuzla Valley. Immediately upon basically the commitment of U.S. forces to Bosnia, we had to find places to stay, and one of the first places we chose was where the Dutch have been staying since 1993. Here. And so we put our forces here in February of 1996 and pulled our

forces out of here in August of 1996.

We continue to have logistic support contractor, Brown and Root, occupy this location. This is a coke plant where they get coal converted to coke and then use that as feed stock for the emerging, what I would say are organic chemical manufacturing throughout the Tuzla Valley where they're using coke and coal oil feed stock as opposed to things like petroleum, natural gas and the like. Lots of residues, lots of waste, lots of places where we don't know where the stuff went to.

At the same time we put people, we have a glue factory in Guardian. Back here, this is further up the valley, is a coal-fired steam plant. And every time we have a unit rotation through here we answer the question about the nuclear reactor right there because there's a hyperbolic cooling tower. And in the United States the only places that use these kind of things tend to be nuclear power plants.

And so we have written probably eight informational papers. We just take one and update it all the time saying that this really is coal, that the smoke coming out of that is not radioactive, it is simply steam, and that what this thing is doing is

just cooling the water and that's how they're making electricity for keeping the lights on.

We continue to do stupid things like we take medical waste incinerators and we put them, I think it was right here, in this little hole here, and we say it's a medical waste incinerator. First, that's really an overstatement. It was mostly a burn box. We put it there and the smoke tends to go right there, and every now and then we have, I think at that point, it was the Swedes and then the Administrator of Defense from Sweden called Secretary Cohen to find out what the hell was going on in Bosnia.

And so again we're having some difficulty maintaining basically commitment to preventive medicine because of location policy. The theater is starting to get mature, the theater is starting to get hardened, and efforts and concerns are maybe getting sort of lackadaisical.

To give you a feel, we have baseline data at every U.S. location that we've occupied to date. However, we don't have any current ambient air data since April of 1999. That's the last time we had ambient air data. The equipment is still in theater.

And given some recent occurrences over there in terms of some exposures to some hazardous materials in an occupational setting and some turnover in preventive medicine personnel, we expect to see that data start flowing again.

Most of the attention regarding this area has shifted towards Serbia and Kosovo, and yet we still have a large number of forces that are here. And you've seen that, this before, but to give you a feel for it is that we're still having -- and what this is, for those of you who haven't seen it: this is a representation for the summer of 1996 for particular matter less than 10 microns by location. And then what we did is compare that to the U.S. EPA national ambient air quality standards for PM10. If it exceeded the standard of greater than 50 micrograms per cubic meter on an annual basis, it was red. If it approached the standard 40 to 50, it was amber. If it was less than 40, it was green.

We have the bulk of our forces in the amber to red area, and the snapshot again through April of 1999 is the air quality has not improved. In a lot of places what it actually has done is started to degrade mostly because industries that

have not been running are now running as the situation stabilizes.

So we continue to have, one of the challenges that we continue to face, is again every time we do unit rotation out there we have to explain what that black soot that settles on your tent every morning is. And so that again shows us that we have some issues.

This is one area where I don't know if we've ever showed this to the board in the past, but it also has raised an issue in terms of our, what I would call, our force protection program beyond our force health protection program.

In Tuzla there is a chlorine manufacturing plant which uses a chloralkilide process with lots of elemental mercury. They take rock salt mined from below Tuzla and make it into chlorine gas. They then combine that with some of the coal oil and the like produced at other places for synthetic organic chemical manufacturing, PVC and the like.

While we are concerned that there was a large quantity of chlorine gas located at this site, we were concerned about what would happen if that

large quantity of gas was released, either accidentally or intentionally. We have modeled that again under a worse case situation. Most of the time the wind goes in the exact opposite direction. Only under some rare atmospheric conditions do we ever have wind in this direction. But one of the nice things about this is we were able to at least assure them that, the current command staff at that point, that they were in no immediate danger in terms of lethal conditions or even in terms of exceeding an OSHA short term exposure limit.

At the same time you could not have a proxy for anything beyond an occupational limit, so we use ACGIH time-weighted average for chlorine and determined that we were within the bounds of that which may indicate that there may be a noticeable effect. Whether that effect would exist long enough to cause harm would be a different story. We are using this kind of information actually to change the way we've cited locations in Kosovo. So that was a very good learning experience for us.

You probably have been briefed dozens of times on the DOD instruction in terms of joint medical surveillance. Just to remind you that the

piece that we're working is identifying potential hazards and evaluating actual documented exposures. And to give you a feel, if you have not seen it, it is available through the clinical business area's website and you can get access to it there.

And again here we are in terms of the group that has formed to work what we're now calling environmental and occupational health surveillance to make sure that people understand that it's environment with a big "E." It includes the work space as well as just the ambient environment. The JESWG -- Joint Environmental Surveillance Work Group -- performs the direction. Executive membership of all these organizations -- the CHPPM, the Air Force's analog -- is to provide health risk analysis.

Probably the last time I briefed this, I said get three unit systems wing. They have since changed their name, formerly EntreLabs, formerly the Occupational and Environmental Health Laboratories, so they've just basically undergone some name changes. The Naval Environmental Health Center, Armed Forces Medical Intelligence Center and then J4 Medical Readiness Division.

In terms of other members, we have

Colonel Diniega from the AFEB has been participating. We have ACOM, limited participation from SouthCOM. We have the AMED Center and School. We have the Air Force Secretary for Environmental Safety and Occupational Health, the Army Secretary for Environmental Safety and Occupational Health, and a myriad of other players.

Some of the current activities that I'll just go over and then give you some examples. We have what we'll call multi-service implementing instruction. In draft, we call it the joint service instruction. That has been dispatched within the past two weeks for review. Again, a lot of those comments, Commander Wayne McBride, Navy BUMED, is the action officer on that. One of the things that we did in the interim waiting for that to come out is we looked at DODI 6055.1. That's the DOD instruction for the DOD safety and occupational health program, and I'll talk about that. But basically we expanded the scope and applicability of that.

I'll talk a little bit about how the environmental health intelligence is improving. I'll give you some examples in terms of operation and joint guardian of current operations in Kosovo.

Where we are in terms of improving the type of equipment we can use to capture some of these exposures, and then talk a little bit about some of the deployment health risk assessment guidances that is now available.

Real quick, basically what we are trying to come up with is a way and a mechanism to implement at the service level and unit level all the various policies out there in terms of health surveillance, and there are quite a few of them. And particularly within the Army we have a challenge in that just because we have a DOD document does not necessarily mean we have an Army policy. I'm amazed every day when we figure that out, and so now I am in the process of trying to backfill from the DOD all the way down to the unit within the Army.

The Air Force and Navy do not seem to have those kinds of administrative requirements as much as we do. Several of my brethren in the Navy might disagree. These are the kinds of things that we're trying to write instructions for. Again, here is the website where they are available.

Basically the clean thing about this that works is, this goes in terms of roles and

responsibilities. It defines what a deployment is, and again this is not final, so those definitions can and possibly will change as we go along. But the big thing about us that it's done is it's taken the concept of what's called "operational risk management" and applied it to deployment health risk assessment.

One of the big challenges we have within preventive medicine is taking the risks that we're concerned about and communicating those risks to the line commanders in a terminology that they are used to seeing. Operational risk management is that terminology. To give you a feel, this is the Army Citation Field Manual 100-14. There is an analogous Air Force and Navy guidance out, and the Marine Corps has augmented the Navy guidance with some more Marine Corps-specific type case histories. But basically what we are doing is assessing risks by assessing severity. And these are defined, but they're defined very broadly. So one of the challenges that we're going to face in the next year is coming up with environmental occupational health appropriate definitions and where they fit, but essentially simplistically catastrophic: somebody dies,

negligible, everybody is okay. That's very simplistic.

Probabilities ranging from unlikely to frequently. And then you assign things. Risks range from extremely high, which is washed out here, but it is black. We consciously used the color codes because in an operational environment, if a situation is black, it means something to a line commander. Red, amber, and green and the like. And so we find ourselves starting to use words like, "You've exceeded ambient air quality standard for particulate matter; you're in an amber status." That's a subjective assumption and judgment. Making that statement, we're trying to come up with the tools necessary to do that.

What we've also done, and I talked at little bit about this, is during the revision of DODI 6055 a year ago last summer, we expanded the scope of DODI 6055 to apply to all military deployments. Prior to this, essentially the DOD safety and occupational health program stopped at the fence line. And so consequently when we deployed we didn't bring our safety and occupational health program to the field with us.

Now, the Air Force and the Navy did a better job, particularly the Navy because the Navy were always where they always are. What was garrisoned floats essentially for them, so it wasn't a big switch for them during military deployment. They already had their IHOs and EHOs onboard ship with them.

For the Army this is taking a cultural change because what we tended to do, if we're standing in mud, obviously OSHA doesn't apply. That's sort of the attitude. Fixing that and changing that culture is going to be a challenge. Again this is where it's at. This also talks about applying operational risk management to safety, occupational safety, occupational health. And so those are the concepts that we're working with right now.

To give you a feel for how we've improved, we actively predominantly have improved the ability to take a look at potential hazards in deployments. This is the Kosovo region of Serbia. Pristina is the capital. The U.S. sector is predominantly in this. This is predominantly the Brits. What we did in terms of this is for the first

time we actually submitted a formal intelligence requirement request through the system, through the COLISEUM which is the cooperative on line intelligence system for end users and managers, not my acronym.

AUDIENCE MEMBER: I'm impressed.

MR. RESTA: I think the "S" may be wrong. I think I got the "S" wrong.

But basically what that did, is that actually tasked the entire intelligence community and raised the issue of we're concerned about environmental occupational health threats. The first time it was ever done, and obviously we did not do it right the first time we submitted it. It took us a while to work that process. We talked to people who never heard of us, never heard of anything associated with preventive medicine. And once we explained what we were looking for, it turns out that yes, we do have some information that would help your situation.

At the same time AFMIC had completed tier one of their process to try and prioritize industrial hazards. They had been working with Johns Hopkins University on it at the School of Public Health where basically they came up with a prioritized list of

hazards. They took that, they took other things and made, published this, and there was actually a DI, a Defense Intelligence report subsequent to 24 March which actually was for the first time in any operation where we had actual environmental hazards, locations, quantities of chemicals, types of chemicals, and the like.

What we did at that point is we did that and essentially did a preliminary industrial hazard assessment, what we call it where we took a look at okay, if we had an accidental release, which way is it going to go? Simplistically, we looked at things like just drawing concentric rings at five kilometers. We also looked at things like using North American Emergency Response Guidance and transportation related accidents to give them a feel for where they were qualified. It taught us some things in terms of that, how to handle things on the classified side.

One of the things preventive medicine has not had great experience with is the field of classified information. You can do the work, but you can't tell anybody about it, or you can do the work and you have to give it to somebody in Europe,

but they don't have classified facts, or they don't have this or they don't have that. And so it identified for us the need to upgrade some infrastructure throughout the community.

At the same time, for the first time we came up with some recommendations for additional entry environmental health surveillance, where we actually said, okay, if we're going to go into a location, here is what we think we ought to be looking for.

To give you a feel for it, this is unclassified, to give you a feel for the kind of information that is available that was not available several years ago, at least not available in a simple place. This is an overlay and that's sort of washed out there, but this is an overlay essentially of the environmental profile of Kosovo. What we have here are high levels of ambient air pollution, and you can see that right here. We have things where we have actual -- we're seeing damage to the forest due to air pollution, mostly acid rain-type of things that we're seeing there. We have a qualitative assessment of the overall water quality, such that if we're going to rely on these water sources, we would know

what to do with it. And we also have some assessment of what essentially the potential for contaminated soil is. There are analog classified annexes to this that go into much greater levels of detail that actually have some use in terms of planning.

We have also completed some miniaturization and modernization of some of our equipment. This thing right here is a PM10 particulate metal less than 10 microns. It's what we have been using to collect essentially ambient air particulates. It's as big as me, it's at least as tall as me, but luckily I don't weigh 136 pounds. It requires consistent electrical power. We actually did get some stuff that ran on 50 Hz, but one of the problems is that consistent electrical power is at a premium in a military contingency.

We went out thinking that we might have to go with the R&D folks to come with something better. It turns out the EPA has been wrestling with the same problem and owned half this patent with a private company for a small battery-operated particulate matter sampler. And instead of pulling through an 8-1/2 by 11 filter, it pulls through a 47 millimeter filter. It only weighs 18 pounds, it's

only a foot and a half tall, and it runs on batteries. And oh, by the way, we can program it to store 96 hours from then, such that we can go and hang it on a pole and not have to worry about it and it will draw samples.

So basically through a cluster of these things we can collect essentially a week's worth of data without having somebody standing there waiting for it. These are deployed in Bosnia right now. We're using them successfully last spring. And we're ready to deploy them in Serbia when that call comes. At the same time we've had great success in terms of simplifying the logistics associated with collecting more quality data.

In the back here is essentially the number of containers you need to fully characterize the water supply using EPA methodology. It's about a gallon and a half by the time you're done. You add the ice and you add the cooler and this thing weighs 50 pounds. You can get essentially one sample point for every regular size cooler.

Logistics, it was difficult. At one point there was probably about 200 coolers transferring the Atlantic between Maryland and

Germany, and Germany and Bosnia, going back and forth. We have coolers, 50 coolers in Edgewood, we had over 50 coolers in Germany. We had more coolers than Coleman does some days. And yet what happens when you have limited transportation, it's difficult to actually get that.

We got with our laboratory people and said we are concerned about these parameters. Tell us the minimum amount of volume you need for the analysis. They actually again went out to EPA and EPA had the same concerns as us and said you really don't need four liters to do a radiological screen, you only need 120 milliliters. And so we went from a gallon to four ounces.

Pesticides one liter down to 40 mils and the like. So instead of having this here, we have this. We continued to try and simplify this because even though I think at one point we're at -- it's 19 bottles. Actually there's some blanks that you carry, but 19 40-mil vials. We actually think we can get it down smaller and maybe come up with something simpler than a 40 mil vial that we can use to actually collect some samples. We're embarking this year on some stability tests to determine if I fill

it up and I don't refrigerate it, what happens to it. But again to simplify a lot of the logistics.

This is probably I think the biggest accomplishment we've had this year. It is our first volume of our first effort in terms of developing chemical-specific exposure guidance that is suitable for performance. Our concerns are applying ambient air quality standards or EPA standards that are designed for the whole population. It might be inappropriate in terms of they're so overprotective they could restrict our operational needs, where someone thought that ambient air greater than 50 microgram per cubic feet is red, I can't operate in that area, when in reality most of the Baltimore-Washington area exceeds national ambient air quality standards at least during the summer for ozone.

So for the most part it was an inappropriate use to just apply EPA standards. Conversely just taking occupational standards, TWAs, TLVs, something like that might be in appropriate because we don't have just an eight hour per day, five day per week exposure, you know, basically you have a 24/7 exposure for nine months of the year.

So taking that, we developed this where

we're looking at exposures of one hour, one day, up to 14 days, and we're putting various levels there so individuals can get data and assessment in terms of risk, negligible harm, up through significant risk. Essentially being able to tell us whether it's extremely high, high, moderate, or low risk. That's published. We're in the process of putting this on the web, on CD as well. And if members are interested we certainly can get you copies of this.

Where we're going, again I'll go over this and then tell you how it will be done. To do this it requires, and within the Army in particular, what's called the DTLOMS approach. DTLOM stands for Doctrine Training, Leadership, Organization, Materials, Soldiers report. It needs a comprehensive approach. We're in the process, and I'll go over how we're going to do that.

NBC defense, the Department of Defense has got a contract on the street for $300 million for chemical agent detectors that they want to have measure industrial compounds. We have not integrated this effort with that effort yet. We have Presidential Review Directive Number 5 as well as Public Law 105-85 that are mandating the evaluation

and documentation of what's called low-level exposures. We don't know how to handle that yet.

Again we continue to fight the challenge of linking this with the health outcome system such that we can actually do some environmental epidemiology, and I think you've heard from Colonel Dennis this morning, we'll continue to fight the IMIT battle. Tomorrow I'm fighting that battle.

To give you a feel for where we are strategically, these are the objectives that are in the medical readiness strategic plan that we're trying to tie our activities through and to. That's important in terms of programming funds, that if you can tie something back that MRSP has paid, you have a better shot at getting it funded than if it's just a real good idea that has not really been accepted by the Department of Defense.

And so these are the kinds of things that we're trying to tie them to, particularly here, the second one, as well as this part right here. Again, that's available there. At the same time in terms of doctrine, the way we're trying to crack that, U.S. Army MedCom floated an issue through what's called the Functional Area Analysis -- Functional Area

Assessment program, FAA program, where the Vice Chief of Staff of the Army basically agreed that there was no doctrine to fill the gap between occupational standards in peace time and full blown major theater war standards, that gap in between. The concept there, we're using words like NBCE, nuclear biological chemical environmental. Navy is using an initialism of CBRE which is chemical, biological, radiological, and environmental. The Air Force, I have not heard their initialism yet, but it'll probably be different from both the Navy and the Army's.

Bottom line to this is that the leadership of the Army realizes that there is a policy and doctrinal gap at the moment, and so now we have the line side of the Army energized to the fact that we do need that, and that's very, very important for us because we can think it's a real good idea, put stuff down on the street, but if we don't get the line buying in, it doesn't get done.

At the same time the Chemical Center and School realizes that they need to start to play, and this will be our entre into getting this integrated with our NBC defense. They have drafted a plan, that

they call a campaign plan under Secretary of the Army. It was campaign plan Rosticker. Dr. Rosticker was the special assistant for Gulf War illnesses, now also the Under Secretary of the Army, and he realizes that there needs to be some doctrinal shake-up.

Some of the things that they're taking a look at is they are taking a look at basically force protection in an NBC environment. They've further defined what an NBC environment is. It goes down to levels of NBC agents or mixtures of NBC agents with other toxics at levels below that considered to be causing harm by the DOD, and also they want to make sure that these are applied through home line defense initiatives, i.e. domestic weapons of mass destruction and those types of issues there.

At the same time Congress is helping us. This is from the authorization conference report under PL/105-85, but basically we have been directed to modify chemical warfare policy and doctrine to protect against any exposure of chemical warfare agents to include exposures to low levels of chemical agents. And then here is where we have some attorneys involved and other toxic substances in the environment that endanger the health of the exposed

personnel.

There is some debate going on. Are we looking at these toxic substances independent of whether there are chemical agents there, or does chemical to chemical agents need to be there for us to really worry about this. And that's going back and forth because there is some funding initiatives that are dependent upon it. But basically we've been told to worry about low levels, even though currently operationally we don't feel that low levels are causing any current considerations.

To get there, I've talked a little bit about our 230A or short-term guide. We have a long-term guide, two weeks to one year, that is currently in the works now. It should be out by second quarter, this FY -- next FY, as well as taking a look at some common Army occupational sources and control recommendations. So we can take a look at where we are in terms of the kinds of occupational hazards we face during deployment, cleaning, equipment maintenance, and the like.

PRU5, if you have not received a comprehensive brief of PRU5, I would recommend that you get one. You won't be able to get it from me

because I don't understand what it's going to do. What we do know is that the President has directed DOD, VA, as well as Health and Human Services to develop comprehensive life-long medical record of illnesses, injury, care, inoculations, and exposures to hazards, and that's our guidance. They've formed a work group, that work group came out with a report, and now that work group has formed what's called the Military and Veterans Health Coordinating Board that is standing up as we speak. Currently there are two individuals that are there, Colonel Craig Postlewaite is Director of the Department of Health, Commander Ed Marcinik is director of research, Colonel Ken Hoffman I don't think is en route yet, but next week I think he leaves Korea or the week after to come back. They are forming various working groups here that will start having at least, if not oversight, review and input to DOD policies, practices, tactics, techniques and procedures.

We're very unclear what this is going to do. Certainly they are very concerned, particularly the people at the VA are very concerned about delayed-type health effects as opposed to operational significant health effects. Our current doctrine,

our current way of fighting, we're concerned about current health effects, how we do that.

And we've seen that. I've talked about that. You know, we've seen that. The big one is the TMIP. Colonel Dennis did not talk about TMIP, the theater map information program. That's the big issue right now. We are building this database system to handle basically all kinds of medical information in the theater as part of the theater map information program. We have this other effort back here in accordance with the comprehensive health care system, CHCS2, or version 2 of that. And we believe that communication is going to be a big challenge, and actually we're starting an operational requirements document review tomorrow in San Antonio.

With that I'll take questions.

DR. PERROTTA: The fastest talking guy in the business. Thank you, John.

Any questions?

Mr. Resta?

MR. RESTA: I'm really going to hate to do this, but this may be my last chance, and John may not be the guy to answer this, but I have wrestled with this picture. We're talking about Khamisiyah

now, however you like to say that. Maybe Greg, who may be behind me, can think about it as well. I have a very difficult time, in fact I find it impossible for me to be able to consider that there was a pile or more than one pile of rockets that may or may not have been filled or partially filled with sarin or cyclosarin nerve agents. I can understand that as a possibility.

And the vision that I have when our own military blows them up to destroy them is that we get a big blow up. I find it very hard to comprehend how we can have all of this sophisticated plume modeling, with 20,000 people potentially -- and everybody skips over that word "potentially" -- exposed when people who are right there, people who are in a more concentrated area, unless this thing went up two miles, which I don't think we have the explosives to do that, and we got no hits on any of the detectors. We've got nobody who suffered any obvious, direct, acute impact as a result of cyclosarin or sarin. And so I am completely stumped on how we can do anything epidemiologically or otherwise based on an exposure that I find, in my perhaps naive and uneducated ways, absolutely physically impossible. Help me, Greg.

CAPTAIN GRAY: Actually, we published a paper using Dr. Broderick's report in fact to choose some diagnoses most likely to be found for sub-clinical exposures, causing chronic diseases. You know, there's just no literature to support that. It's not been tested in a way. So you're right, it doesn't make -- there's not a lot of biological data to support such an impact.

So what we were doing in our analysis and what they're trying to do here is to set up a mechanism so that we can rule out things like that.

DR. PERROTTA: And I understand this is not a scientific question. It clearly feels to me like a political question. We have very smart people spending scarce resources on studies that are going to be, in my opinion, fatally hampered by a theoretical and, yet to me, not physically possible exposure to an agent that we certainly should have seen something else go on. And I don't mean to demean the work you're doing at all or demean what you're doing at all, I just -- help me or tell me to shut the hell up. I guess I should shut the hell up.

COLONEL BRADSHAW: I don't know if this will help any. I'll just mention that there have

been some things come through that are posted to Gulf Link -- sorry, posted to Gulf Link through the web site that they have that looks at some of the modeling. They actually blew up some rockets that were similar to this, modeled how much went into the sand, how much went up, you know, in the explosion and so on. So if you want to look at the physical likelihood of contamination, that is available on the Gulf Link Website.

CAPTAIN TRUMP: Although I think you stated the underlying issue is, you know, politically we are in a position of at least trying to prove a negative, which is that there is no evidence of any adverse effects from any exposure that may or may not have happened. There's a challenge and the best we can do is when we're asked to do that is apply the best science we can so that, you know, over time hopefully the weight of evidence will show us what is the correct situation. But, you know, it is frustrating for all of us when, you know, there are other issues that are quite pressing.

DR. PERROTTA: Well, my issue is not whether or not we should try to prove health effects to an exposure. My statement today is I simply

cannot understand the physics that there could be an exposure in the absence of anybody showing the acute -- I mean, if you know what we know about nerve agents is that the no effect to an acute hit, the eye changes and pulmonary changes and the rhinorrhea and all that, is a little one that goes current. There's very little underneath the effect level. And so, if you think about that, what you're saying is we blew up a bunch of bombs that supposedly had this stuff on them and yet we never exceeded this level because we never saw anybody who had any of the rhinorrhea or the shortness of breath and the pinpoint pupils, and so that everybody else in the entire theater or wherever had to be exposed to things at less than that level. And I find that physically impossible.

And I don't know, maybe I'm beating a dead horse, but in epidemiology it's hard to do work when you don't know what the exposure is or when there is no exposure. And we'll be saying an awful lot about that in our review of the physiolostigmine bromide report, and maybe that's why it's an acute problem to me. And I'm turning this thing off.

MR. RESTA: One thing that may be of value to you, they potentially had part of the

Presidential Special Oversight Board's of that critique submitted. Sometimes they don't seem to have those kinds of problems. We also share a lot of your same sentiments, yet they seem to make these great jumps and leaps of faith without any problem whatsoever.

DR. PERROTTA: A whole raft of epidemiologic studies being supported by DOD and perhaps politically driven is about this particular incident. And without an environment exposure, it feels like an extraordinary waste of money.

MR. RESTA: We're also embarked on doing similar things, including rain as well.

DR. PERROTTA: I'm sorry, Dr. Anderson. Did you have a question?

DR. ANDERSON: I do have a question and the question I have is more regarding the modeling in that you show your plume, but a plume assumes, I mean you can move that plume around the world with any model. Just giving it enough time and transport. It more has to do with the concentration. So the question on your plumes, what was the concentration that you used to draw your boundaries for your various plumes, or was it a time thing or --

MR. RESTA: Well basically it was concentration time, but we can go to a concentration. There were two zones. The first zone ranged from lethality down to what we could consider myosis level. The CT on that was one milligram minute per cubic meter. And then the second zone we defined as low level was one milligram in a per cubic meter down to a concentration time on the 72 hour general population control level that was established for worker protection back in 1989. The concentration of that was one times ten to the minus fifth milligram per cubic meter. The CT based on a four hour exposure was .015 milligram minute per cubic meter.

DR. ANDERSON: The assumption was that all of the material was dispersed.

MR. RESTA: No, no, not immediately.

DR. ANDERSON: No symptoms, we had no lethalities, but your modeling has to start with a concentration that you then --

MR. RESTA: Disperse.

DR. ANDERSON: Yes.

MR. RESTA: And the way it was dispersed, and the way it was dispersed it was not dispersed instantaneously, it was not a puff model. Because

based upon the dugway test we found that stuff actually potentially pooled and then dissipated actually over four days. And so the plume I showed you here was the day one. We actually have day two, day three and day four, and see you can with the changing meteorology --

DR. ANDERSON: Yes.

MR. RESTA: -- the thing would shift and then, you know, at the end it's just a real little, essentially octagon as the source term, as the source dissipates. The one thing that is nice at this point in time, based upon current unit location data, we had nobody within the zone where we would have seen noticeable effects. So at least our version of history and our version of the mathematics of the situation currently coincide. However, changes in unit location database could change that or change any of the source terms in terms of either the amount of agent that was present, or the wind was blowing, or direction, how fast, could push you over five kilometers and all of a sudden you have 300 people that should have noticed something.

DR. ANDERSON: Were any animals looked at?

MR. RESTA: I'm not aware of any laboratory based --

DR. ANDERSON: -- no, no, I mean wildlife? While there may not be large animals in the desert, there's a lot of small animals that you would have thought had there been a major exposure.

CAPTAIN TRUMP: I don't think there was anything there to be concerned about. There were --

MR. RESTA: I am not aware of any actual data --

CAPTAIN TRUMP: -- not a lot of little skeletons there.

MR. RESTA: -- on this situation. There were some mathematical exercises.

DR. PERROTTA: It was good to see you. Sorry I got off on --

MR. RESTA: Okay.

DR. PERROTTA: Any epileptics in the off room?

DR. ANDERSON: We'll find out.

DR. PERROTTA: We will find out. This will be the armed forces epileptic screening program. See if your medications are still working.

Should we move the break up? Okay, let's

take a 15 minute break. Five after.

(Whereupon, at 2:47 p.m., off the record until 3:05 p.m.)

DR. PERROTTA: Captain Greg Gray is from the Naval Health Research Center and is a friend of the board and has been involved in Board activities or we've been involved in his activities, I don't know which way, for many years, and I appreciate his participation and support of board work, and I'll be interested in hearing some more about ARD updates.

Greg?

CAPTAIN GRAY: Thank you very much. Is this on? Good.

What I'd like to do today is tell you a little bit about what we're doing to survey for emerging respiratory disease. At the Naval Health Research Center, San Diego we've recently been able to establish somewhat of a reference laboratory. Can you hear me now? How about this one? It never fails, I run into these technical problems. Okay, how is this?

At the Naval Health Research Center we've established a respiratory disease laboratory. We have a number of assets in virology and in

bacteriology that we're developing and adapting molecularly at least such that we can assist in various outbreak investigations and cohort studies. And I want to talk to you about our surveillance work and some of our cohort studies too.

Just to show you where we are today with some of these studies, you can see that we have some, I think 19 different military commands involved, a number of them major military training commands, that include lately the Coast Guard, the Army, the Air Force and Marine Corps, and of course the Navy. We're working on liaisons with the Mexican military to establish some surveillance with them as well.

I want to talk to you out about three of the agents we're looking very hard at. First of which is streptococcus pneumoniae. We have surveillance at seven military facilities for this pathogen. We take only invasive isolates and those include the patients that are both active duty and dependents. We're looking at the antibiotic sensitivity and also looking at their serotypes because there were some public health implications particularly among the active duty personnel.

You can see that our data with respect to

penicillin and erythromycin resistance is similar to this being seen across the United States, that is that we have a high prevalence, and much of the potential resistance of multi antibiotic resistance. You can see though importantly and one of the reasons we do this surveillance is that geographical distribution of antibiotic resistance differs by site, so it's very important for us to consider these differences when we suggest policy decisions.

Here you see that Great Lakes has so far really no evidence of antibiotic resistance. We have quite a bit in San Diego and in Washington, D.C. Perhaps the only place in the DoD that can type pneumococcal isolates, and here you can see that you can type a number, I think 55 here, and we actually have more, but I don't have the data, but it's important to note that here that all the clinical isolates we received so far have been in the trachiavalent vaccine.

The second pathogen I want to mention is streptococcus pyogenes has long been a problem among military populations, particularly trainees not only for rheumatic fever but for pharyngitis outbreaks and recently some of the more invasive manifestations

like toxic shock and necrotizing fascitis. We have eight military recruit camps providing us with specimens. We don't take every specimen, but we take a certain number of specimens per population per week to do, again, resistance testing. And we collaborated on this one using new molecular techniques that we hope to adapt to our lab.

Looking at emm-gene, this is much more sensitive, if you will, or we're able to type more than we could through the traditional NMT type that was done years ago where you could only get about 50 percent. Fortunately we're seeing very little antibiotic resistance among the clinical strep pyogenes although the erythromycin resistance seems to be increasing somewhat. And you can see again the geographical distribution of that antibiotic resistance varies by training camp. But Texas had more than their share.

We're just learning about this emm typing so I mean I can't give you profound conclusions regarding this, it's a whole new nomenclature organized and led, spearheaded by the Center for Disease Control and Prevention. But basically we're finding some serotypes on the types that you would

expect in our populations.

Finally I want to tell you a little bit about our viral respiratory surveillance. We began this work in October of 1996 with start-up monies from BUMED to look specifically at adenovirus. We transitioned the study from May of 1998 looking for all causes of febrile respiratory illness and that's what we call the surveillance now.

The concept is rather simple. Well, I think I passed out handouts, you have before you, when you take the specimens out. We take the throat cultures from all the trainees that come to the clinic with a temperature of 100.5 Fahrenheit,or higher. Just a throat culture, they are preserved at minus 70 C and shipped in batch to NHRC where we work them up for up to a total of 28 days and then we can do indirect course antibiotics implication and serotyping.

So for the time period I've showed you before we actually collected quite a few isolates, let's see, in the neighborhood of 3,300 isolates, that's a whole lot of throat cultures that came through out door, and a very high yield which concerned all the cold chain problems was quite

remarkable. And you can see that the yield differed by the four sites that were successful in sending us specimens with some of the highest percentages being MCRD San Diego locally.

The proportion of positive specimens varied over time and increased in the winter months in almost all the camps, reflecting winter adenovirus epidemics. And you can see that when we had those epidemics not only do we get more specimens reflected here in tan, but we also get a higher yield, in some cases as much as 100 percent of the specimens came in positive for adenovirus. So this reflects massive morbidity. We don't have time to go into it today, but there have been recent papers or papers in press documenting epidemics recently in both Great Lakes and at Ft. Jackson, thousands of trainees affected when we stopped the vaccine either from lack of supply or administrative purposes. And we are anticipating some really bad winters while we procure a new manufacturer for vaccine. If you want more information I think Colonel Hoke is here somewhere and he has the latest scoop on that in trying to get a good manufacturer for adenovirus vaccine 4 and 7.

It's important to note we saw some real

differences here geographically as well with types 4 predominant at these three camps, and type 7 predominant at Great Lakes. This is new, I don't know what to make of this, but it seems to be somewhat stable in that 7 seems to be the most prevalent at Great Lakes over the entire period of time. It's also important to note that type 21 does have a clinical impact here. If you remember that type 21 was tested but never manufactured.

Here's some data that I think very well accurately show you what has happened since we've lost adenovirus vaccine. This is Ft. Jackson, and you can see that using the routine control program of employing the adenovirus vaccine, we really didn't have a lot of febrile respiratory illness, but when we stopped the vaccine for various reasons, the febrile respiratory illness rates escalated, and it's hard to predict where we're going to go this winter.

We do know in this study that trainees who did not receive the vaccine were 28 times more likely to be positive for types 4 or 7. So the vaccine still seemed to have pretty good clinical impact.

So we transitioned this work, and when we

transitioned it we stopped taking every culture from every trainee, and that's because it was just overwhelming in our lab. So now we have again we're sampling based on the population strength at the site. And again the specimens come to us in batch. We went from four sites to nine sites, and proudly we just most recently added the Coast Guard's training camp. We also studied folks at Ft. Benning because Ft. Benning is a very dynamic population in a sense that they're often deploying and we think that they might bring in some unusual adeno types.

The case definition is very much the same. We now use two cell lines, 8549 and Rhesus monkey kidney cells instead of just 8549. And we do IFAs for a number of different viral pathogens. We're one of the few places that the DOD that not only can type adenovirus, but along with Dr. Leonard Cass's lab we also use CDC typing service to type influenza.

Here you see some of the data that we post on the web reflecting the participating sites. This is the Army's epidemic threshold rate, which is based on cases, febrile respiratory illness cases per trainees per week. And you can see that Great Lakes

have a problem here, and I think that's Lackland, is that Lackland Air --

DR. PERROTTA: Ft. Jackson.

CAPTAIN GRAY: -- Ft. Jackson had a problem here, and we seem to be having a problem right now in fact. So we're closing watching this. Some of the Cape May data down here, you were shown some of that yesterday, so they really don't have a marked problem.

I got a call last week from Vicky Fogelman who you will remember was the former secretary here that said there was an outbreak in the freshman class at the Air Force Academy and wondered what we could do to help.

Looking at the first 835, some cultures we have seen, you'll see the predominant organism has been adenovirus, this is in contrast to some of Linda's work that you will see later, with some flu A and flu B recalled it. Most all our trainees received the influenza vaccine. Finally again the positivity differs by site. We may have a pool chain problem here, we need to check on this at Ft. Leonard Wood. We seem to have more negatives than some of the other sites. Again we post this up on the web so

that the public health officials can decide, you know, what they should do empirically when they have outbreaks.

Finally, using these same data denominators were able to not only calculate febrile respiratory illness rates, but using the portion of samples that are positive for a particular type of package, in this case adenovirus, we were able to determine the adenovirus rates at the camps.

Because of the base line surveillance and the techniques we've developed we're able to do cohort studies. The Navy Surgeon General will sometimes ask us to do a study among the freshman class at the Naval Academy because they had three years of unexplained respiratory disease outbreaks. We followed these trainees into May of this year and it looks like we didn't have the epidemic that we anticipated, we had a bump here in the curve when they first came, but we really didn't see the 400 cases or so we expected. Nevertheless it looks like mycoplasma explained about 20 percent of these. We're continuing to work up some sero.

The Basic Underwater Demolition Schools had some problems with pneumonia and necrotizing

fascitis and one or two cases of streptococcal toxic shock over the last three years. They have asked us to see if we can figure out what's causing their pneumonia. And it was decided through collaboration with them and infectious disease docs and a lot of pressure from some of the senior policy officials to do something that we would try to come up with clinical trail of azithromycin. This is one gram per week to cover the two weeks of Hell Week which are most suspected or most associated with pneumonia and necrotizing fascitis. It's a double blind two agent placebo controlled study. We're about half way through it. I believe we've enrolled 300 trainees at this time.

Finally I'd be remiss to not tell you about this. Ft. Benning has experienced a second pneumococcal, we think pneumococcal outbreak early this year. 29 cases of pneumonia among the Ranger trainees, which are similar to the SEAL trainees based at underwater demolition school. The CHPPM did a carrier study and found rather high prevalence of pneumococcus and we've studied it and found it to be chiefly serotype 9. And there they responded with some azithromycin, mass prophylaxis, and pneumococcal

vaccine and are trying, they've proposed another follow-on study among the following classes to determine the clinical effectiveness of using the pneumococcal vaccine in this population.

Greg Cohen and Claire Broome and I have also proposed a large pneumococcal study. We hope we will meet with some success in a review that's underway to use the pneumococcal vaccine in a placebo controlled way to study its clinical impact among recruits at five training camps. I think their number is 167,000, so it will be rather ambitious. We'll see if there is the funding to do that. But the idea is, you know, the pneumococcus continues to raise it head, and cost prohibitive would it be cost effective for us to employ the vaccine, the 23 day vaccine.

Finally, just to give you a snapshot of what we could do at our lab, this is in your handout, I don't go into it in great detail, but we've developed through some of gracious collaborators like Dr. Joe Gaydos, his wife Charlotte, at Johns Hopkins and Gail Castle at University of Alabama in Birmingham, they transferred technology to us so that we're one of the few sites that can do a number of

things, for instance with mycoplasma pneumonia and with chlamydia pneumonia. And also I should credit David Schnerd at California State at Berkley lab for showing us sero tracking techniques.

For closely collaborating both with the State Lab, with adenovirus and influenza. Recently some of our colleagues at Ft. Bragg discovered or detected the first H1N1, one of the first H1N1 isolates influenza A isolates in the U.S., and Dr. Henry at the State Lab typed it for us. And CDC has been calling us because of this GEIS sponsored repository we have of adenovirus and it seems that they are having a very big problem with pediatric adenovirus deaths in the

Chicago area, and we found it to be a subtype of 7 that they are postulating might have changed over time. And anyway we're going to send them about 50 isolates for molecular studies.

Finally we're hoping to adapt some new techniques which we'd be able to do DNA fingerprinting of some of the streptococcal isolates. We've submitted a grant, and I think it's funded to improve the diagnostics for bordetella pertussis, another problematic pathogen, and we're evaluating or

hope to evaluate in cooperation with Quidel a rapid bedside colorimetric test for influenza.

Finally, this little commercial if you want to know more about our studies, you have a pretty good website for the DOD hub for Global Emerging Infectious Disease System, which has sponsored this work in its entirety now for about three years. And I'd be more than happy to assist you with more information. Thank you very much.

DR. PERROTTA: Are there any questions for Captain Gray?

Mark?

DR. LaFORCE: The Ft. Benning outbreak with the 29 cases, how many of those were documented as being due to strep pneumo?

CAPTAIN GRAY: I think only a handful. Now, the investigation conducted by the general, there's somebody here who can speak better on that, was done retrospectively and it was a carriage study, but I think they only had a couple clinical isolates among the 29, two or three, something like that.

DR. LaFORCE: Any bactiremic cases?

CAPTAIN GRAY: That's where I think they got their isolates.

DR. LaFORCE: Okay, not from sputum?

CAPTAIN GRAY: No. I may be wrong on that. Does anybody know these data better than I do?

LIEUTENANT COLONEL WITHERS: No, I can't. I think it was more than a couple, but you're right, it was --

CAPTAIN GRAY: It may have been mixed sputum culture too.

Yes?

COLONEL HOKE: You mentioned earlier about the vaccine and said that I might comment on that. Some months ago the Defense Department made available a source of funding with which we, the Defense Department, was to seek a manufacturer. The job of doing that came to the Medical Research and Materiel Command and Mr. Bill Howell there is responsible for that activity.

A request for statements of interest was published on the Commerce Business Daily website about four or five months ago. Four or five companies came forward expressing interest in manufacturing an adenovirus vaccine, none of the major manufacturers, despite the fact that there may be, you know, untold benefits in larger markets than

just the DOD.

Nevertheless, there are some companies that are interested in manufacturing this vaccine. We are continuing to work with Wyeth to obtain the production information from that company. It's been slow going, but not entirely their fault. And we expect that an RFP will be issued fairly soon for actually formal proposals from candidate manufacturers. Obviously "tempus fugit."

DR. PERROTTA: Anybody else?

I know you have an airplane to catch.

CAPTAIN GRAY: Thanks very much.

DR. PERROTTA: It was good to see you again.

CAPTAIN GRAY: Okay.

DR. PERROTTA: Okay, next we're going to hear a clinical update on the combination of hepatitis A and hepatitis B vaccine in Twinrix. Dr. Parenti will join us to introduce Dr. Abraham.

DR. PARENTI: On behalf of SmithKline Beecham I'd like to thank the board for the opportunity to discuss our combination hepatitis A and hepatitis B vaccine. And I'd like to ask Dr. Betsy Abraham from my division to present the data to

you.

DR. ABRAHAM: Good afternoon. My name is Betsy Abraham, and I am one of the medical monitors in SmithKline Beecham. I work in the vaccines division and I'm an associate medical director there. Dennis is my boss and I try to do everything that he tells me to do.

We will be reviewing the technical data on Twinrix, SmithKline Beecham's combination hepatitis A/B vaccine. After we review the product profile I shall be spending a few moments on why you need to consider adding the hepatitis B vaccine to your contract on the basis of hepatitis A vaccine.

In the interest of time I will not be going through every single slide that you have in your handout. I will be doing a selection of the slides, and if you have any questions, I'll be quite happy to stop and review whatever slide we need to.

Twinrix should be a familiar vaccine because the two antigens that compose it are extremely well-known to us. The hepatitis A antigen is marketed as Havrix in the United States, and the hepatitis B antigen is marketed as Engerix-B. The hepatitis B antigen dose in Twinrix is the same as in

the Engerix- B, i.e. 20 micrograms of HBsAg. The hepatitis A antigen in Twinrix is half the adult Havrix dose 720 Elisa Units/ml instead of 1440 EL.U/ml.

Twinrix is administered on a three dose schedule of 0, 1 and 6 months. These two antigens are adsorbed onto aluminum salts. The target population is adults who are 18 years of age and older, who are at risk of hepatitis A and/or B and who are not previously immune to the disease either due to earlier disease or by vaccination with either monovalent vaccine.

During the manufacturing process, the two bulk antigens that compose Havrix or Engerix-B individually, are formulated into Twinrix. The two purified bulks are added on to aluminum, the antigens formulated as the combination vaccine, filled, and packaged. This slide shows that following absorption and the additions of water for the injection, a preservative, 2-phenoxyethanol is also formulated in the vaccine.

The following slide show the regulatory status of Twinrix. It is approved in several countries around the world, excluding the U.S. It

was approved in the EC through the centralized procedure in 1996 in an adult formulation, and in 1997 as a pediatric formulation. It is also licensed in 12 countries outside of Europe which includes the UK, Canada, Australia. Twinrix is currently under review with the FDA for adults aged 18 years and above.

We generated data on the safety, reactogenicity, and immunogenicity of Twinrix in 11 clinical trials. The methodology that we used in these trials was identical, and was the standard way of conducting clinical trials that we and other manufacturers follow. For safety and reactogenicity, we looked at solicited local and general symptoms for four days following each vaccine dose. We also recorded unexpected or unsolicited symptoms and signs for up to 30 days after each dose. Both solicited and unsolicited symptoms were recorded on diary cards by subjects and handed in. Serious adverse events were reported through the entire study period and until 30 days after the last vaccine dose.

We bled almost all subjects for the evaluation of immunogenicity. There were a total of 1,800 subjects that you will see data on. The time

points were at baseline, just before the vaccination, a month after the first dose, (the two month time-point on the slide is one month after the second vaccine dose), just prior to the third vaccine dose (that is month six on the slide), and then one month after the last dose, (month seven on the slide). Month seven data were used as end-points for assessing the performance of Twinrix.

The laboratory assays were standard too. The anti-HAV assay used was an ELISA test and was a commercial kit from Boehringer-Mannheim called Enzymun. The anti-HBs was a radioimmunoassay (RIA) called AUSAB. We look at the results in two slices, the safety which is an integrated summary from 11 trials, and the immunogenicity also integrated across all trials.

This slide shows the demographic profile of the 1,800 subjects in the 11 trials. Most of them were female, about 65 percent, and 85 percent of all subjects were aged 40 years and younger, between 18 and 40. However we did have 15 percent of subjects who were aged 40 and older.

The total number of subjects that received one dose was 1,812, our safety database.

The total number of doses administered over 11 trials was 5,331. Forty-five percent of subjects reported soreness, of which 0.3 percent had grade 3, defined as not tolerable. Redness was remarkably lower. Swelling was just about 10 percent. These symptoms were transient and self limiting and did not last longer than two days.

The most common general or systemic side effects that we saw were headache and fatigue. Both symptoms are less than 20 percent. Again grade 3 symptoms were very few, 0.6 and 0.5 percent. There was some fever, fever being recorded as temperature above 37 degrees C. There were no reports of grade 3 fever, defined as 102 degrees Fahrenheit or above.

This slide shows the general safety profile. Of all the serious adverse events that were reported through the 11 trials, there were none that were related to the vaccine. Similarly, of the several unsolicited adverse events that were reported, upper respiratory infection was reported the most, but again we could not discern any factor that showed that something a pattern of relatedness to the vaccine. There were withdrawals due to adverse events; however pregnancy was the most common

cause of withdrawal, since pregnant subjects are not allowed to continue in the trial. There were no deaths during the course of the trials.

Immunogenicity was studied in many different ways. Production lots are tested for consistency in clinical trials. Three consecutive production lots were proven to be consistent with regards to the reactogenicity and immunogenicity profiles.

ON the following study, we will see comparative data of Twinrix with its monovalent components. Twinrix was administered to one group, and the other group was given Havrix and Engerix-B. You will also see the overall antibody responses to Twinrix in all studies. Thirdly, you will see data on the persistence of antibodies following Twinrix compared that lasts long enough to the persistence of antibodies following Havrix or Engerix-B. Finally, we reviewed data to investigate if combining the A and B antigens causes interference in the generation of antibodies against these two antigens.

There were 893 subjects in consistency trials. All trials were double blind and subjects were randomized to one of three groups administered

on of three production lots. On the handouts, you'll see the actual date for the A and B components. You can see that the numbers are remarkably similar for all three lots. In fact, for hepatitis A seroconversion was close to 100 percent at month seven and GMTs were in the 5000s in all three lots. A reference rate of 95 percent seroconversion to anti-HAV was used. All subjects in the analysis were A negative before the intervention. Seroprotection for hepatitis B was defined as the percentage of subjects who were sero-negative before and achieved 10 units or higher after Twinrix.

A clinical equivalence limit of ten percent was used. Seroconversion to hepatitis A, seroprotection to hepatitis b and the GMTs induced for both anti-HAV and anti-HBs were shown to be statistically equivalent.

The next slide shows data from the comparative trial in which 773 U.S. subjects were enrolled. The aim of this trial was to study whether Havrix and Engerix-B as compared to Twinrix would produce similar reactogenicity and immunogenicity profiles. This was an open-label trial and subjects were randomized into two groups. One group received

Twinrix and the other group was administered Havrix and Engerix-B concomitantly. The objectives of the trial were comparative safety and immunogenicity.

The overall compliance for the 773 subjects was 99 percent, indicating the number of subjects who returned diary cards. Half of them were 40 years of age and older and half were between 18 and 40 years of age. There were more females than males in both groups, but the ratio of male to female was similar in both groups.

In this slide local reactogenicity data in the U.S. trial are shown. Soreness was reported with a frequency of 38 percent, of which only 0.5 percent were grade 3. The results on giving Havrix and Energix-B together resulted in a higher percent of sorenss, 46.1 percent. The numbers speak for themselves. Redness was quite low but similar in both groups. Swelling was also quite low, and Twinrix seems to induce about one percent less of swelling.

As for general reactogenicity, headache and fatigue were the most commonly reported symptoms. There were slightly more reports of headache with Twinrix. Fatigue was also a little higher. Other

symptoms such as nausea, diarrhea and vomiting were similar in both groups.

GMTs and seroconversion to hepatitis A were higher following Twinrix than after Havrix and Energix-B.

At month seven following Twinrix, sero protection to hepatitis B was 95 percent, which is what we see as our usual value for Engerix-B. Antibody titers, were slightly lower than usually achieved because half the subjects were 40 years of age and older. On separating the data into those older and younger than 40 years the younger subjects had higher titers than those 40 and older.

Ninety-two percent of subjects were protected against both A and B if given Havrix and Energix-B separately; however, ninety-five percent were protected against both diseases when administered Twinrix.

The next slide shows overall antibody responses to Twinrix in the 1,551 subjects from whom all blood samples could be analyzed at months one, two, six and seven. Seroconversion to hepatitis A was 100 percent and the GMT was very high, 5,000. Ninety-nine percent of subjects given Twinrix had

sero protection to hepatitis B, with GMT close to 4,000. Twinrix appears to induce immunogenicity that is as good as, if not a little bit better than the component monovalents.

We studied antibody persistence. Subjects who had been enrolled in previous trials were requested to return for yearly blood draws. A total of 129 subjects were available for analysis at month seven. The two graphs demonstrate that the decline in antibody titers following Twinrix was similar to that following either Havrix alone (2 lots, 2 lines) or Energix-B alone (2 lots, 2 lines). So the antibodies persistence seemingly is similar levels.

The following slides address the question of whether there was interference in antibody generation due to the combination of hepatitis A and B antigens. Trials from our data base were selected if the same investigators from the same sites had performed earlier monovalent trials, so that data collection and study conduct occurred under similar circumstances.

In this slide, the top row indicates clinical development. First Havrix was administered

alone, followed by Havrix and Energix-B given concurrently. Next, we syringe-mixed the two monovalents. Finally, Twinrix was formulated. Havrix alone induced titers in the range of 4,000s. When A and B were given concurrently in opposite arms, titers were in the same range as Havrix alone. When both were syringe-mixed, titers were higher than Havrix alone. Finally, Twinrix induced high titers. The set of results is indirect evidence that there is no interference on combination.

For hepatitis B, again the same plan: Engerix-B alone, Havrix and Engerix concurrently administered, next syringe-mixed and then Twinrix. There are outliers, values 10,000 and 1,000, which are not unusual for a hepatitis B response.

Since the seroprotection against hepatitis B is 10m IU/mL, all values are well above that value. When Energix-B and Havrix were given concurrently the titer ranges from the 3,000s and 4,000s (mIU/mL). When syringe-mixed titers are close to 4,000 so it's in the same range. When Twinrix is administered alone anti-HBs titers were still higher.

The following is my last slide on the product profile. The final question we asked

ourselves was, "How functional are the antibodies produced? For anti-HBs we were not able to devise a test to answer these questions, since there is no universally accepted test currently.

For anti-HAV, we showed that neutralizing antibody titers were similar to the titers tested by ELISA. The same correlation was performed with a Twinrix study. Once again neutralizing titers similar to ELISA were produced. Lastly, we picked two epitopes raised monoclonal antibodies against them (which are shown here) and they appeared to be similar to the values of those monoclonal antibodies which I am showing as data here. Twinrix and Havrix seem to induce antibodies against the same epitopes, in a similar order of magnitude, thus confirming the functional and neutralizing quality of the antibodies raised against Twinrix.

Let us take a step back. Twinrix is safe, has an acceptable reactogenicity profile and it performs very well in regards to immunogenicity. What does this mean? We like the fact that you recommend hepatitis A for the forces. The question now is, "Is there a particular reason that you should consider adding hepatitis B?"

Consider that perhaps the situation for the armed forces is not the same as when policy was made a while ago. You know about this far more than I do. From the news I glean, it seems evident that forces are called in to serve in situations now that are not purely active combat. Peacekeeping or humanitarian relief often demands that forces have to be deployed where hepatitis B is endemic. All it takes for HBV to be transmitted is the presence of infected blood or body fluids, and a cut on your skin, a break in skin continuity or an abrasion.

Consequently, many of these infected individuals will become chronic carriers who are passing the disease on. Eventually they will become quite sick and be moved from active duty into the VA system.

The next slide shows a few quick statistics on hepatitis B that you probably already know. Ten percent of those who are infected are at risk of becoming chronic carriers. Twenty-five percent of them progress to chronic liver disease. Persons with chronic HBV infection are many times at higher risk of getting hepatocellular carcinoma, with about a five year survival rate for HCC. One article

states that the time to cirrhosis in patients with chronic active hepatitis is five years.

There is also more recent data on co-infection of hepatitis A with hepatitis C; this can be potentially deadly, with fulminant hepatitis. There is also one paper showing that co-infection with hepatitis B and C seems to produce an enhanced cytopathic effect.

The last bullet on the slide is somewhat intuitive. There is already liver damage from one infection (with hepatitis C) and one does not wish to place the patient at greater risk with fresh hepatic infections.

Here are some data that I got from Dr. Schiff who works at the University of Miami. According to him, in a study that was done across the U.S. in the VA system on two days, eight to 10 percent of those tested have hepatitis C.

To conclude, it seems to make sense to us at SmithKline Beecham, that the armed forces should be protected from both vaccine-preventable hepatic diseases. As you have already seen, the safety profile of Twinrix is comparable to well-accepted monovalent vaccines, and the immunogenicity profile

of Twinrix is at least as good as the monovalent vaccines. Thank you.

I'll be happy to take any questions.

DR. PERROTTA: Thank you, Dr. Abraham.

Are there any questions?

David?

CAPTAIN TRUMP: Yes, Captain Trump. Just one question. On the U.S. trial you mentioned Havrix. Clarify for me, you're talking Havrix 1440 - -

DR. ABRAHAM: Yes.

CAPTAIN TRUMP: -- at zero and six months.

DR. ABRAHAM: Correct.

CAPTAIN TRUMP: Okay.

DR. ABRAHAM: Plus 720.

CAPTAIN TRUMP: Right.

COLONEL ENGLER: Do you have thimerosal in Twinrix?

DR. ABRAHAM: We have trace amounts in the bulk of the hepatitis B antigen.

COLONEL ENGLER: So the final product is maintenance Hep B or --

DR. ABRAHAM: Yes, the final product has

a trace amount.

CAPTAIN TRUMP: But you have to be 18?

DR. ABRAHAM: 18 and above. Yes, it's an adult product.

DR. PERROTTA: Dr. Music.

DR. MUSIC: You presented data to say that you have this licensed in 12 countries, but you didn't show any post marketing surveillance data for this product in those countries. Could you comment on that?

DR. ABRAHAM: Yes. We do have plenty of post marketing-surveillance data. I didn't bring it along. I think generally the idea is that we don't see anything in Twinrix that's different from Engerix and Havrix, and in fact we haven't seen quite as much as Engerix probably, because Twinrix has been much more recent. But if you would like the actual data, we could send it to you. Would you like me to send it to you?

DR. MUSIC: Let me talk to you about that afterwards.

DR. ABRAHAM: Okay.

DR. PARENTI: Is there a particular issue that you're looking for?

DR. MUSIC: I just wanted to know why it was missing.

DR. PARENTI: Oh, all right.

DR. PERROTTA: Anything else?

Okay, thank you, doctors for coming. I appreciate you taking your time.

Anybody who is taking a look at your watch will know that we're not going to finish as suggested, so let's do the best we can in asking pertinent questions and staying on time.

Up next Ms. Linda Canas, Canas, help me, Canas, is back from Brooks Air Force Base, from my home town.

MS. CANAS: Thank you very much. I'll be talking about influenza surveillance, a program that's been going on for some time. And as you are well aware the Department of Defense recognizes that the trivalent vaccine is the single most effective way to prevent influenza illness in our troops, and that's true if the vaccine matches the prevailing strain. So it's in everyone's best interest that we take advantage of any kind of surveillance opportunities that we have.

Now, just to give you a real broad

overview of how this program works, samples are collected from patients meeting the case definition at our sentinel sites. They use collection kits that we provide and they're sent to the laboratory at Brooks Air Force Base. Usually this happens by Federal Express. We work them up as a virology specimen, report anything we get back to the base as a patient report. Plus by electronic means we notify the public health officers so they know what's going on in their location. Selected isolates then are antigenically sub typed in our lab, shared with CDC and now we're also doing molecular sequencing.

Now, just to give you an idea of what the scope of this program is that we're talking about, this is presently the sites that we're either receiving or expect to receive samples from this year. And we don't just take stars and throw them up on the map and see where they land, we actually have some very definite criteria.

We've selected sites, one of them is training centers, and those are individuals that are coming together from a variety of different locations, at the same time are usually crowded together, probably living and working together, and

they could be bringing their own virus. And in this environment we want to make sure that we identify a respiratory outbreak very quickly and identify any influenza that might be there. A special note here is we've been doing Lackland Air Force Base all along. Our's is an etiologically based program.

Greg Gray who spoke a little bit ago, works with the respiratory disease program population based study. So beginning this year Lackland is going to be sending all of their specimens to NHRC. And now the two arms are different. We're doing etiology, Greg is doing population base, and his is doing a very defined population. It was nice to know that his graph, or even the graph that I have that he has, but you can see that his has been mainly an adenovirus in the recruit population, where our's has been more of the influenza.

Another category are those -- well, we have one on location. The mission here is those are more strategically located. Usually they're overseas in Asia where the prevailing theory is that the new emerging strains will originate. Also these are individuals who will probably be deployed in and out of areas that are strategically important. So we

have a very heavy emphasis on this particular locality.

And I seem to have skipped over one, and that's the ports of entry along the coasts. Each of the coasts have bases that we have individuals, whether they be active duty or tourists who are coming into the country may well have been in an area where they've been exposed.

And then we have what we call our special sites, and this has become a very exciting part of the program, and we're taking advantage of the fact that the Army and the Navy have research labs in remote areas of the world. And generally these are areas that are under-surveilled in the world health organization, so we're moving in and adding our protocols sometimes that are existing to collect febrile respiratory illness samples. We are routinely receiving samples now from the Nepal and Thailand, and in South American from Peru, Argentina, Ecuador, and this year we'll add Bolivia.

I have added to your handout at the end of my slides, a list of those clinics in those various areas so you'll have an idea of the diverse populations and clinics that we're servicing in these

areas. This has been very valuable in our surveillance program.

Now, what do we get from all of this. We got all these sites out here, what is it to our benefit? If we group them now geographically and look at the specific, this particular year which was this year, we started out in December, these were the first isolates we have in influenza. It was a late year, we really didn't get going. Generally we start out our first isolates come from Guam and Andrews Air Force Base, but this year they were from Osan. And also they started out as A. Virtually all the As this year have been A/Sydney H3N2. There was a group from the Yakuska Naval Station that we got a group of H1N1s, so those were interesting. And all of these samples besides the fact that we do sub typing, we share these with CDC.

The other problem we're having right now is we know that influenza V/Victoria is over in Asia. It's sitting over there and hasn't moved and everyone is a little nervous about when it is going to move. So there was a heavy emphasis on keeping track of the Bs. We sub typed 42 from this area, they have all been the B/Beijing 184 which is the

vaccine strain.

From Europe we've got or first peak of Bs. They started coming late in the year and moved. We got them first out of Germany and the UK and before we were able to see them over in our country in the United States. And in the U.S. we've listed the bulk of our specimens. Most of them came from here. We pretty much mirrored what everyone else was seeing. The most significant outbreak we saw was this year in March from the Air Force Academy. Just before spring break there was an outbreak of influenza B in that population. All of these typed out as B/Beijing.

So our year, don't worry too much about this. What I want you to notice here, we do have most of these colors A and B, B influenza, but there are a lot of other colors here that are represented in this graph is other respiratory viruses, and we report anything that we get and that's just to show you there are a variety of different viral isolates which of course is what impacts on people's perception of how well the vaccine may work for them.

Twenty-five percent of the isolate specimens we work up are positive for some kind of a virus.

But if we focus just on influenza we can see that we have a peak, it was a fairly dramatic peak in January. It was actually at the very end of January of influenza A, and then we started up again with our peak of B, and the real difference this year that we haven't seen before is this late summer peak of influenza A. We had just finished working outbreaks out of Panama and at Lackland Air Force Base.

The Defense Language Institute there where they train foreign students, this group was from Puerto Rico, they identified an influenza using one of the rapid tests and called us, sent the specimens to us and we were able to quickly isolate them in tissue culture and assure them that they were a vaccine strain. None of these particular students had been vaccinated. Intervention measures were started immediately, the disease did not get out of this particular student population, which is very good for the community.

This is just an overview of some of the outbreaks that we had this year. I mentioned Lackland. And there was a cruiser the Navy reported, in one meeting I called it a cruise ship, it was a

cruiser, and they laughed too. They reported that 80 to 100 out of the 300 individuals on board were showing respiratory illness. They sent us 11 samples and we recovered three isolates, all of those being the A/Sydney H3N2. They were able to find out that these individuals had not been vaccinated, they had in fact fallen through the cracks.

Now, some of the things that we, from looking back on this year, it was definitely an influenza year. Of the nearly 20 percent of the isolates were influenza, and 72 percent of those were influenza A. The vast majority of those were H3N2. And this is a little bit of a nervous point too because this has been true for the second year now, and there is nothing on the horizon that should alert us that we have another influenza coming in and that will be the component for the vaccine next year. Historically no virus had predominated for three years, and this will be the third year for A/Sydney, so we're watching it very closely.

The Beijing was the only B subtype, and as I mentioned we're watching it very closely too, but so far that's what we've been seeing everywhere.

There were a few H1s that I mentioned

that we got out of Yakuska. We also got some H1s out of Peru. And a subset of those were variant. The CDC tells us they've only seen twice before, once in LA last year and once in LA this year. Since, I think there has been one in San Diego also. So these H1s, there are very few being seen around the world. There's some thought that perhaps the H1 is going away. There are still low level indications and we'll certainly watch all of those isolates very closely.

To my mind the biggest success of the program this year is the recognition of what we can do. There have been twice, two times now that we've been contacted by CDC of reported outbreaks in remote areas, but they have had no access to specimens. Both times we've been able to contact people on site and to get specimens from them.

The most dramatic example recently was in Panama. They said that they had this reported outbreak. I called the lab officer at Howard Air Force Base, they were in the last weeks of closing that base and he told me he wasn't even sure they had individuals who could collect viral specimens. But in fact they did, they collected 24, had them shipped

to us, we isolated the virus, sub typed them as H3N2 and shipped them off to CDC in a two week time frame.

The same thing happened in Nepal earlier in the year. We did not recover any influenza from those samples, we got some Para 3. But we just two weeks ago got a large shipment of incoming from Nepal from samples that were taken from March through August, and we have 50 some isolates when I left them last Friday with a last look, and those have been sent to CDC as soon as we have the isolates, so that they can gain any data they can for the vaccine meeting that will be meeting next week for the southern hemisphere.

And that was one of our high points too. For the first time the Department of Defense was asked to report directly to the Vaccines and Related Biological Products Advisory Committee meeting on our results. And certainly our data has been used in the past because we have shared our information with the CDC, but we actually presented in person. And the scope of our program is impressive.

And what we reported mirrored what the rest of the countries were reporting, and that was important, but what seemed to create the most

excitement and what generated the discussion afterwards was the fact that we have a very unique population and it provides us with an opportunity to look at vaccine effectiveness.

We have a diverse population, both in demographics and geography. We require them to be immunized and we can track that. So this was the question, can you look at this as a whole population and help us decide how effective in any given year this vaccine is? Can we use this information? Is that really possible? And of course the unspoken caveat in there is, with existing resources and that we actually can get at the data that we know we have.

So where we're going to start trying this year, we have been trying to match this up in the past. We've tried to match up our positive cultures with the patient vaccination status. We were able to do that with 60 percent of the cases this past year. Once place where we really were able to use it was in Osan, there was an outbreak there. We determined that 89 percent of the cases were in the active duty population, and in fact 83 percent of those individuals had been vaccinated.

We're going to identify a randomly

controlled group that we will now do vaccination status with those individuals and then hopefully be able to do the vaccination status of those with a positive culture result. It takes an awful lot of man hours and searching to get this vaccination status. It is totally dependent on the local bases, updating the records in a timely fashion.

We're going to then take these breakthrough isolates, the ones that we know are isolates from a person who has been vaccinated, and we're going to do some molecular characterization of those viruses. We're going to sequence them, can we tell something from the sequence that may make it obvious that there is a difference from the vaccine strain?

We just sequenced a group of isolates from the Lackland study, the DLR students, and they all are exactly alike as we would expect. The next step will be to compare those with the vaccine strain and with the Panama strains. Panama was having their outbreak right about the same time, so that's the next step in studying from that group. The molecular work is the new part of our study, and we want to see what it is we can identify with these. And we are

working with CDC so that we're not doing the same ones. The plan is to share the information and establish a library of the sequences of the various flu around the world.

And as everybody does now we have our web page. This actually isn't available yet, but we expect to be a link from the GEIS page which has been funding this program and also our own web page at Brooks Air Force Base.

And just to summarize, those of you who know me know I've used these slides before, and one of the challenges with influenza is we just never know what to expect. And here it is now in the middle of September and we have no clue what kind of season is ahead of us. We know that's a fact because we have data from past years. We've put together a series of slides from '92 to show the personality of each influenza years. I just want to quickly go through those for you.

We used to have years like that. This was when we first started seeing the B coming late, and this past year, okay, so that was this past -- oh that was from our special site, those flus that we got from Nepal and South America. And those are a

little difficult to analyze the way we've presently done them because the collection time and the time we cultured them would be so far apart.

We think this is a good program, it's given us a lot of valuable information over the years, and as more and more bases we've tried to become more responsive to the bases. One of the things we want to do with this web site is to give monthly updates on what's going on, we would like to tune into it. And we're also wanting to do base specific reports so they can tell exactly what they are doing and how it fits into the total picture of what's going on around the world.

I talked to my peers and they say oh they've had a light year, they've had an A year or a B year, well that's in my mind like, you know, what part of the elephant did they touch. Our's is a worldwide program, and we're trying to see what happens through the whole year.

Are there any questions?

DR. PERROTTA: Any questions for Linda?

Art?

DR. REINGOLD: I think your study looking at influenza isolates is interesting, and the

question I had is about the case control study. Can you tell me what proportion of the military is vaccinated?

MS. CANAS: The Air Force reports 90 percent of the population is vaccinated. I don't know the other services.

DR. REINGOLD: Obviously -- vaccinated we won't be able to use these --

MS. CANAS: Yes, it's verifying, we say 90 percent, but we want to verify that they have, that's the problem we have.

DR. PERROTTA: Other questions?

Okay, thank you, Linda. I hope we're getting some rain at home.

Next the Military ID Research Program, Colonel Charles Hoke.

While we're waiting, board members and guests are reminded that we start at 7:30 tomorrow. That's in the morning. We will take attendance. And board members and others, would you like to go to dinner this evening?

Greg, are you available? Sue, any problems?

COLONEL HOKE: Thank you very much. I

very much appreciate the opportunity to address the board.

The Military Infectious Diseases Research Program, of which I am the manager, is farther up the pipeline than some of the things you've been hearing about. We basically are working to develop products for problems for which there are not very good solutions yet. And I think it's a good idea to periodically talk with the board, we haven't had the opportunity to do it in a number of years, to let you know what things might be expected.

Our mission is to conceive and implement focused and responsive infectious diseases research and development for the Department of Defense leading to effective technology for protection and treatment of the warfighter in medically hostile environments to maximize operational capability of deployed forces. We're virtually constrained to work on things that are not licensed.

The obviously infectious disease threats hardly need any definition here, endemic or newly emerging, capable of influencing the outcome of military operations by producing excessive morbidity, morality, morale disturbance or consumption of

resources.

The program is a joint service program. The Army is the congressionally directed lead agency. And the research development, testing and evaluation is directed by the commanding general of the U.S. Army Medical Research Materiel Command at Ft. Detrick, formerly MRBC, it's now called MRMC.

The basic research for which I am responsible is carried out, is managed by our program office and coordinated with the group that tests the products that are invented, which is USAMMDA. We call that advanced development. We proceed with a solution, invent it, and then they test, they organize the testing, which is coordinated in part because it's the same scientists that end up doing both.

Our work is conducted at Army and Navy labs by Army, Navy and Air Force military and Army and Navy civilian scientists. Department of Defense oversight is provided by the Armed Services Biomedical Research, Evaluation and Management, or ASBREM, Committee which is chaired by the Director of Defense Research & Engineering and the Assistant Secretary of Defense for Health Affairs. The JTCG-2,

which is Joint Technology Coordinating Group, provides joint service input to this program.

There are lots of stakeholders. We get military requirements from the AMEDD Center and School, and TRADOC the Navy Bureau of Medicine, from the Air Force, and we certainly get input from the Office of the Joint Chiefs of Staff, the medical branch there. The coordination, as I mentioned, is through the ASBREM which looks out for all the service needs.

Our funding comes from Army S&T, Science and Technology funding, and advanced development funding comes from a different part of the Army, leading to enormous amounts of confusion. We get funding from different places and I'm not sure these people talk to each other. The Navy provides some overseas lab funding for overhead types of issues in the overseas labs. And I mentioned about the staffing and other matters. So we live in a very complicated environment trying to please lots of people.

We have a budget of about $52 million each year. After everybody, this is after everybody has taken their taxes, that's what's left to

distribute. And you can see that a lot of the money, about half of the money is for infectious diseases research, 27 percent for HIV, WRAIR overhead gets about a quarter, and we have some Gulf War money for a study of leishmaniasis.

Our facilities are worldwide, and in fact a number of the items that were mentioned in the previous talk have actually been piggy-backed on the available laboratories that the Military Infectious Diseases Research Program has supported for many years. Our principal facilities are here in this area, here in the Washington area. WRAIR and NMRC, the Research Center have been co-located now in a single and beautiful new laboratory facility not far from here in Forest Glen, Maryland. USAMRIID is at Ft. Detrick, and we have a small effort there which requires high containment.

The Navy has a lab in Peru, and in Cairo and Jakarta. The Army has labs in Thailand and Kenya. And it's this lab here that has a lot to do with collection of the specimens in Nepal that were mentioned. Each of these laboratories you might say branches out to the areas around the laboratories, and in one recent lab commanders' meeting we had

epidemiological reports from many of the countries surrounding our laboratories, and so you see we can get information from a large number of tropical countries.

Now, how do we prioritize our work? One thing we do is we look at past military engagements where different kinds of diseases have been either an important consideration or actually have manifested themselves as significant epidemiological problems. And one can see diarrheal disease, a repeated theme. Dengue, a repeated theme. Hepatitis, going back some years. And malaria as a repeated theme. And we integrate this information along with some other information like this about soldier's lives and the different kinds of risks that affect military people at different points of time in a military career. This is just one of many ways of sort of parceling out the complicated infectious diseases problem to determine what you might feel is important.

There are many diseases here. You can see them. The ones that I have shaded in bold face are the diseases that we are still working on in our program. A number of these diseases, influenza, adenovirus for example, we've played some role on in

the past and we don't have them actively in our research program now. I should have bold faced HIV because we do have a very active program there.

As solutions are found, for example for hepatitis A, we heard about Twinrix, and I always like to take every opportunity that I can to mention that the hepatitis A vaccine was in fact invented at the Walter Reed Army Institute of Research. And the minute the SmithKline vaccine was licensed, people at Ft. Detrick called me when I was in the laboratory and asked for all the money back, so that's the way the DOD moves on from one thing to another.

So our program then for FY01 is prioritized like this. Our principle effort is in malaria vaccine research and in drug discovery, and then the prevention of diahrreal disease, flavivirus vaccine research, and this is mainly dengue. And diagnostic systems, our principal interest here is to be able to develop a system where say large numbers of individuals in a deployment who appear to have an infectious disease which might be a naturally occurring infectious disease or might have been induced by biological warfare, there needs to be a way to sort these out because they obviously have

very different political implications. So we have a joint program with the biological defense people to develop a common diagnostic system.

Malaria Genome contributes to these programs. Insect vectors are important for most of these diseases. Hepatitis virus vaccines, meningococcal vaccine research, research on hemorrhagic fever and other highly lethal viruses, rickettsial diseases, leishmania research, and HIV, and that's funded separately so this really doesn't reflect its priority to us.

However, for these diseases above it, these prioritized places are very important because we can't afford to do everything and each year our budget gets squeezed a little more and a little more, and the people at the bottom of the list get cut. For example in this year, I should say in FY00 we unfunded our leishmania research, and in FY01 we don't have the money to support rickettsial research or hemorrhagic fever viruses research any more.

We've had a number of successes, and the next two slides will show you both vaccines and drugs that have come out of our program. The Japanese encephalitis and hepatitis A vaccines, and I won't

call adenovirus a success because we know that's a miserable situation right now, but originally it was a success for a while. In IND, we're working with SmithKline on RTS, S vaccine, and we also have a p.falciparum DNA vaccine which is in IND.

We have the world's first shigella flexneri, a successful vaccine protects against challenge. Campylobacter vaccine and ETEC, and we're working with companies that have HIV vaccines and other vaccines are further up the pipeline. A number of drugs have come out of the program, halofantrine and Mefloquine were both Army inventions. And tafenoquine is the most recent malaria drug which SmithKline is developing. It was an Army drug and they have taken it over and have recently decided to accelerate the development process.

Now, just to give you an idea, how do we manage the program? I wanted just to say a few words about that. We have about 250 scientists, 1,000 employees in many labs that I mentioned, around the world, and all of them have a shrinking budget and a long list of things to work on in a very highly competitive environment. You may not know this, but we don't compete in a medical arena for our funding.

We actually compete against tanks and jeeps and weapons for our funding. And they covet this money very much, and so we have to manage it very, very tightly.

And we have a web based interactive program for specifying objectives in our program office and developing those objectives into solicitations by our leading experts, we call them research coordinators. Then we post those as we're doing right now, our solicitations, for internal research proposals that the our investigators develop and submit with their laboratory commander's approval. Our program is entirely peer reviewed. In '01 we'll start that. That is a huge culture shock for our scientists but I think they will be better off for it in the long run, although they remain to be convinced that that is so.

We have internal steering committees that prioritize the science that needs to be done, and we then complete the budget plan and present it to the commanding general for his approval. This whole process takes over a year to develop our plan each year, and then we distribute the funds to carry out the research on behalf of the Department of Defense.

And this is how we invest the dollars that we have. I've told you what our priorities are, but the malaria vaccine for example gets $5 million, and the rest of these things, and I won't go through them in detail, and that funds 20 individual projects. Diarrhea stands out here as having a large number of projects with a slightly smaller budget, but they just divide the pie up into smaller slices.

The kinds of research that we are doing is not basic work. We are very applied. For example, our largest single number of projects is in vaccine discovery. Drug discovery is another large number. The epidemiology we conduct is principally to identify study sites for using our vaccine for testing the vaccines and drugs that we develop. Most of the work is done at WRAIR and NMRC, and these are the overseas labs with progressively less fewer projects.

Now in FY00 this figure actually shows the kinds of transitions that we do. Milestone zero is when we identify a project product, and milestone one is when we hand it off for advanced development. And these products over here are the same as you saw before that are already in advanced development. And

we use this slide just to show the general what we're doing with the $50 million each year. So we expect we will transition vaccines for shigella and we're working to put everything together into a polyvalent vaccine for diarrhea, and you can see the rest of these in your handouts. They're truly just to show you the progress that we expect to have and where we expect to be by the end of the fiscal year. I won't go over these in detail.

Recent accomplishments that we've had is the testing of the RTS,S vaccine, which was able to protect against the malaria challenge and was the first vaccine that was able to do that. That was a huge milestone.

Our Navy people at NMRC, Dr. Kaufman, have worked with a company that developed a DNA vaccine for malaria which has not actually really been shown to protect against challenge yet, but has been shown to stimulate T-cell immunity to malaria.

The same group has been very aggressive in terms of sequencing the malaria genome. Chromosomes 2 and 14 have been finished, and 2 has been published, 14 had been posted on the web. And there was an article in Science this past week which

utilized this information from the chromosome 14 and identified two additional, two new targets for malaria drugs from that sequence data. And of course that's the motive for getting that sequence data out.

I mentioned about the tafenoquine and we recently are completing a very good trial of a malaria diagnostic device which we hope will meet FDA licensure standards.

I mentioned about the shigella vaccine, that's worked out fairly well. That's now in clinical trials in a number of places, particularly in Bangladesh.

HIV field trials are imminent, particular in Thailand. And we also have a group working in Uganda on those. An HEV vaccine is recently being transitioned to advanced development. We are excited about that and hope that our commercial partner continues their interest. Dengue vaccine has been transitioned to advanced development, and we have a DNA vaccine candidate as well, and we have a very exciting candidate hantavirus vaccine that's based on DNA technology.

There are a number of issues impacting on our program. I mentioned about our planning through

the interactive website. This is actually, everyone has a website, this one has been mentioned, but the concept of all these 1,000 people and 250 investigators being able to participate and jointly develop their proposals is actually one that I am very excited about. It's really, it represents a huge acceleration for us.

The technology area review and assessment that is conducted each year has identified that we have significant manpower problems. Most of our infectious diseases officers are beyond 20 years of active federal service and will doubtlessly be leaving soon. We've lost three in the past two months, three of our 18, and so our manpower is shrinking. We haven't hired any civilians or hardly any to speak of in about ten years at WRAIR, and so the enterprise is threatened in that way.

We've been instructed to review the impact of CRDAs on the program. Collaborative research and development agreements are a very powerful tool, they bring you money, usually not very much. Some scientists are put into the lab by companies, and you do identify a potential manufacturer. But from the DOD point of view,

although all these things are wonderful, what you lose is you lose control over the product completely. And if a company decides that it isn't any longer in their interest to work on the product, it will be dropped, you know, and it will be dropped instantly and we'd be left with nothing. So we're looking at the pros and the cons of these CRDAs.

We recently have been requested at the OSD, Office of Secretary of Defense, level to address budget shortfalls. I found out that when high level people ask you to talk about budget shortfalls it's not that you have a wonderful sort of tooth fairy up there that is going to give you something wonderful, what it actually means is you really antagonize everybody in between who it is implicit that they didn't give you enough money. And I thought this was a great opportunity to improve the program funding, but it actually didn't work out quite like I had hoped.

Because of the funding impact, the funding detriments and taxes and things that I mentioned before, we have been forced to terminate funding of many of our research programs. And they are the lowest priority programs in terms of their

clear potential for impact on military operations, but nevertheless it hurts.

So in summary, we have a worldwide joint Army and Navy and Air Force actually research program, uniquely focused on protection of the warfighter. We have a dynamic process to focus and refine objectives, and we're highly leveraged with industrial partners.

That's really all I wanted to say. I just wanted to give you that quick overview. We would certainly be happy to come at some time when we're not so late in the afternoon and talk to you about specific drugs and products, but I don't think this is the time to do that. So if there are any questions, I'd be happy to answer them.

DR. PERROTTA: Any questions for Colonel Hoke?

Yes?

COL. DINIEGA: Charles, I notice hantavirus is very low and, you know, that is one of my pet peeves about the lack of a vaccine for hantavirus, which is one of the biggest threats in Korea.

COLONEL HOKE: Well, the hantavirus

vaccine that I mentioned to you, the DNA based vaccine, was a specific present for you. That work was done entirely for you. And people will always ask well where did we get our requirements, who told us to work on this, and we just keep saying that you said to work on that hantavirus vaccine.

It's very promising and we hope to transition that to advanced development in the next year, and we hope that that program won't terminate. We have to budget realistically and tell people when we run out of money on that priority list, but nevertheless we do hope that some fix will be found before we actually get to FY01. We still have 14 months.

DR. REINGOLD: Actually my question is more to do with funding than with the presentation of Dr. Hoke. This reflects I think some things I've heard from colleagues who work very hard in these same areas, and the frustration over the declining funding for research. I wonder if that's an issue which the board should take a position on or try to recommend or something. Because it seems to me this is a very important area of research which is threatened by this funding situation. Is that

something the Board should undertake?

I'm not asking you to answer, Dr. Hoke.

COLONEL HOKE: I'm not answering.

DR. PERROTTA: Did we not mention something along those lines in our report, Dr. Poland?

DR. POLAND: Let me see how we said that.

DR. DINIEGA: I think that was off when we did the report.

But I'm not mistaken, Charles, the previous, this recent TARA also made that an issue and surfaced that through their chain, that you were under-funded and under-manned and they needed to take a look at how to fix that also. They made recommendations to look at it.

COLONEL HOKE: We certainly would appreciate any support. Technically our funding hasn't actually gone down, but the costs of doing, as we've shifted from kind of a basic science and intellectual discovery to very product oriented, the cost of good clinical practices, good manufacturing practices is much higher, and in addition there have been increased salary costs and overseas laboratories, and other things which have actually

eroded our ability to do things. So we do feel constrained and there is a process within the DOD for competing everything against everything and we're about to enter that cycle for the FY02 to '07 time frame. It's called the POM, program objective memorandum. And as we go in to compete, I would surmise that support from the board wouldn't hurt.

DR. PERROTTA: I recommend that we discuss it in the morning in disease control, and should the wishes of that committee be known, that you bring that up to the full committee.

Thanks again, Charles. It's good to see you again.

Colonel, will you tell me how to pronounce your name?

LIEUTENANT COLONEL GRABENSTEIN: Grabenstein.

DR. PERROTTA: Okay, Grabenstein?

LIEUTENANT COLONEL GRABENSTEIN: Yes, sir.

DR. PERROTTA: Lieutenant Colonel Grabenstein is going to talk about AVIP, anthrax kills, vaccinations protect, absolutely.

LIEUTENANT COLONEL GRABENSTEIN: There's

more on the other side.

DR. PERROTTA: Did you get one?

LIEUTENANT COLONEL GRABENSTEIN: We've got some extras. We've got some more.

DR. PERROTTA: It's the little things that get us excited.

LIEUTENANT COLONEL GRABENSTEIN: Silent training aids is the technical term.

Thank you very much for your time. I was just remarking to Colonel Diniega that when I was a lieutenant I used to slip into the back of the AFEB room when you met in the old building to listen to the deliberations of the AFEB, so it's a real pleasure to be with you today and give you an update on the Anthrax program.

I'd quickly like to cover and remind you of the threat which is the basis for everything that comes later, review very quickly the vaccine and the history and what we know of the safety of the vaccine, both historic and current, and spend time describing our current plans in terms of additional research agenda and answer any questions that you may have.

The threat that of course the nation is

coming to grips with, how to respond to bio terrorist threat, but from the military's perspective, as biological warfare, biological attack is the greatest concern to us. Anthrax, one of the most deadly diseases especially by the inhalation route on par with Ebola and rabies, and of course it's the spores that constitute the hazard from an anthrax weapon because of their stability.

We've had a safe and effective vaccine so judged by the Food & Drug Administration since 1970, and fundamentally similar to all other inactivated bacterial vaccines.

Much of the threat can be seen from the civilian literature. You're probably familiar with the August 6th 1997 review article in JAMA, the website there is the table of contents. The entire issue of JAMA is available on the internet.

Iraq has admitted to the United Nations Special Commission that it loaded anthrax onto weapons. Various Soviet disclosures, if you've not read Ken Alabac's book Biohazard, I recommend it to you. And the entire federal-civilian government working on its own biodefense programs for the civilian sector, Health and Human Services, FEMA in

the States, etcetera. And the web site there for report on anthrax risk, from the working group of the civilian biodefense.

The primary problem with anthrax bacteria is of course from the spores. It's a micro -- you know, microbiology sufficiently I believe, and the problem is the case fatality rates from an inhalation disease is the primary concern.

A federal study establishing the efficacy of the vaccine was published by Brachman in the American Journal of Public Health in '62. Essentially 93 percent efficacy for containing this disease in a placebo-controlled study, but with insufficient cases of inhalational disease to firmly establish statistically, efficacy. Although in a simplistic analysis there was five cases of disease among the unvaccinated group, zero among the vaccines. In a simplistic exact test it's P equals .06.

This vaccine, the Brachman vaccine was modified slightly so that the culture produced more productive antigen and it was that modified vaccine that was licensed in 1970 by a component of NIH that is now within the Food & Drug Administration.

In 1985 there was published a reaffirmation or a reassessment of the evidence of safety and efficacy in the vaccine by an FDA advisory panel. That advisory panel recommended that FDA actually revoke the licenses of several biological products, but that committee found that there was no reason to doubt the safety of efficacy of anthrax vaccine and it was reaffirmed at that time, and FDA accepted that judgement.

So we don't have sufficient, or we don't have sufficient evidence of efficacy against inhalation in humans, but we do have animal data. And the most persuasive probably is that of Rhesus monkeys, and that's four separate studies that in aggregate show that 44 out of 45 of the vaccinated monkeys survived an aerosol challenge. The one fatality was given two doses of vaccine and then challenged two years later and succumbed.

Carl Friedlander at USAMRIID indicated to me a couple of days ago that there is an additional study which will add to this denominator and ratio stays relatively constant so that we have substantial primate model data for the efficacy of vaccine by the inhalation route. And all the unvaccinated monkeys

died.

The vaccine is an inactivated bacterial vaccine. It infiltrates, so in modern parlance we would call it an acellular vaccine perhaps, the principal component being protective antigen, a toxin sub unit of the lethal toxins of the bacteria, it's adrenalin aluminum (phonetic), and given on schedule six doses, zero, two and four weeks, then six follow in 18 months with annual boosters to sustain.

The vaccine has always been manufactured in Lansing, Michigan, although we have had a variety of owners of that plant, along with the Michigan Department of Health. This was the laboratory where two female pioneers of immuninology developed a way of standardizing pertussis vaccine. The remains of MBPI in 1995 were then sold to a private corporation when the state decided it was not in the vaccine business, to BioPort.

BioPort ceased production in 1998, has completely renovated their facility. They are awaiting FDA inspectors to come in and match the blueprints with the plant on the ground and perform the period of potency safety and sterility tests on the lots off of the new assembly line, if you will.

And pending FDA's approval, we will have an additional supply of vaccine. We are currently vaccinating with existing inventory from the previous facility. The estimate upon that is early 2000, but that's FDA decision.

The history of the vaccine is that it was used with a quite small market. Up until the Gulf War there was only about 68,000 doses distributed in that 15 year period, about roughly 150,000 service members got a dose or two during the Persian Gulf War, and subsequently primarily '98 and '99 greater than two million doses of vaccine were distributed.

The Department of Defense plans a three-phased execution of its plans to vaccinate the force. We are at phase one now, which is to vaccinate anybody going for one or more days to the high threat areas, the ten countries that you see listed there.

Phase two we anticipate beginning promptly after the new production line comes on line, so roughly early 2000 again. And that would be early deploying forces. And then phase three for the remainder. So we're in phase one now, and it will take us until about this point to get the entire force, active and reserve, vaccinated.

Today we have delivered just short of 1.1 million doses of anthrax vaccine to approximately a third of a million people. And you see the rows here are in shot by shot about 1,200 have completed the entire series, many of them are Gulf War vets. Some have gone out far enough in time to have gotten a rank, but you can see obviously with the first three doses are predominant. I got my second dose about three hours ago, so if I have a late phase reaction I'll be responding to it.

DR. PERROTTA: Are you feeling okay.

LIEUTENANT COLONEL GRABENSTEIN: I'm feeling just fine.

And you may know the story that we had a vial or two that froze on its way to Europe and they tossed out 200,000 doses for quality control reasons, and subsequently we have designed a state of the art shooting system with a variety of insulation procedures and temperature monitoring procedures so the shipping success rate is now 99. something percent.

Side effects, it's an inactivated bacterial vaccine. My comments about human effects will be based on the Brachman study. The CDC study

which was done with the current formulation of vaccine which was actually a key piece of the licensure material that FDA considered in late '60s and 1970. Ft. Detrick's experience with repeatedly vaccinating workers in the biological, in the black days, the biological offense side, and of course more recently, only biological defense side, the studies from Tripler, Korea, 121st EVAC and a variety of other sites.

It's not uncommon to have, you know, a contained reaction at the injection site. There was about one to five percent having swellings in the three to 12 centimeter range. Less than one percent greater than 12 centimeters. Significant systemic events, this is consistent with the, if a person has defined events as to what amount of reactions you find, the less than one is the level from the package insert for fever, chills, nausea, etcetera. The Tripler data which said that muscle aches is seen by 15 percent of folks, self-reported, but the number missing a day of work is considerably lower than that. So where do you set the threshold for how you measure these events is crucial.

Many of these injection site reactions

come from giving an alimagitive vaccine subcontaneously. So the folks at USAMRIID and Ft. Detrick are working on a study to change the route from subcontaneous to intramuscular as well as to reduce the six dose series to a five dose series. The pilot of this project showed that the injection site reactions, virtually it's fine, it's still optimistic, but were substantially eliminated. So this is a major item of importance in our research plan.

DR. HAYWOOD: Is there a correlation between the local and systemic reactions?

LIEUTENANT COLONEL GRABENSTEIN: Is there a correlation between local and systemic reactions, no, not in any organized fashion. This is primarily, the series adverse events, I'll show you some data on that in a minute, but by and large not related to the magnitude of local.

So one of the things you'll see in the newspapers is that there is no long term studies of this vaccine, which is factually incorrect. In fact the first one was published in 1958 in the bulletin of the Johns Hopkins Hospital. These three studies and I've passed out a bibliography so you have the

full citations, were studies, an ongoing series of studies of the folks at Ft. Detrick, and Colonel Phil Pittman, who many of you know, is working on the update to that series in even greater detail. The folks at Ft. Detrick made up an evaluation that over the years has gained in sophistication from merely a symptom check to a series of lab tests, and in recent years physical examination. And from that data is our largest core of confidence in saying, you know, no systematic long term adverse effects from the vaccination.

And Colonel Pittman is developing a mass cohort analysis looking back in time at many of these employees with matched controls to gain even greater confidence in this.

On August 24th, my office in the Department of Defense posted the first meeting of a longitudinal studies concept. And fact I want to thank Dr. Poland for taking time away from his family to join us. Also we brought in Martin Myers from the National Vaccine Program Office as well as Ron from the Food & Drug Administration VAERS program to give us outside recommendations on how to proceed to, you know, to be able to pin down to what extent, you

know, our assumptions and our reasons, judgements are in fact factually based.

And this committee recommended a set of at least five kinds of studies. A set retrospective and prospective, intermediate studies, and long term studies in each. The NRE wants these surveys of active duty personnel following up on the study of Tripler Army Medical Center to go out a little bit further in time, database studies of in-patient and out-patient utilizations using the RA medical surveillance activities, Defense Medical Surveillance System. And Captain Gray from San Diego is interested in pursuing some of these same kinds of things as well. And Colonel Pittman's look-back study from the special organizational SIP at Ft. Detrick would fit in this category.

And prospectively we are evaluating the feasibility of looking at troops enrolled in VSA individual training grants, officer cadets, to follow them over time, a natural experiment if you will, some will be assigned to units vaccinated early and some will not, and then we can compare. Take some base line surveys prior to their vaccination and then follow them up after their vaccination. And perhaps

also take national survey, national cohort studies of retirees who got vaccinated and those who didn't and follow them forward in time, or people who separated from the service without retiring and follow them over time.

The fifth category is fundamentally different I think, and that is you may know that with the Lyme disease vaccine and the varicella vaccine, manufacturers established pregnancy registries, such as was done with the rubella vaccine in the early '70s, late '60s and early '70s to assess the fertility effects of the vaccination.

I am gathering data on how many women we would need to enroll in the study to make it meaningful, to see if it's reasonable to perform this. Certainly we'll conduct it if it is of scientific value. My personal hunch is that we should just do it for all vaccines rather than just let it be limited to the anthrax vaccine, but that certainly is subject to comment.

The next meeting of this board will be on September 22nd, so if any of you have any comments on this or want any more detail, I certainly can provide that or take your comments back to them.

I was asked to explain the medical exemption system for people who should not get further doses of vaccine, and it's a set of 12 two prior groups medical codes, and this was actually designed so that it would meet any vaccination, not just anthrax so you have any positive rubella titer and being declared immune from the need for rubella vaccination. But for anthrax reactives, the temporary fall weighing well during the course of pregnancy or while awaiting medical consultations, underlying health conditions, etcetera, and a variety of administrative codes so that we can begin to have a little more real time assessment of what's happening with vaccination delivery.

Back to the side effects, every VAERS report, well VAERS is the Vaccine Adverse Event Reporting System monitored by the Food & Drug Administration with assistance from the Centers for Disease Control. Every VAERS report submitted regarding anthrax vaccine, bar none, goes to the FDA for review by the VAERS staff at FDA.

In addition we've asked the Department of Health and Human Services to convene a panel of civilian medical experts independent of the

Department of Defense to review every VAERS form looking for any, well making a causal assessment to the extent that they can based on records of the role of the vaccination. And this slide shows the end of the pipeline, the reports that have gone all the way through that were viewed by the Anthrax Vaccine Expert Committee, or AVEC, and that's, as of a few days ago, 314 VAERS reports.

Two hundred twenty-five of those did not involve loss of anyone in 24 hours, did not involve hospitalization, they are a variety, primarily of injection-type reactions, headaches, tinnitus, malaise, and certain non-duty imperative reactions or events. We're a bit more concerned about the impairment of function, so you see the next two categories. Events that involve loss of duty more than 24 hours, but did not involve hospitalization and events involving hospitalization. And so there were 72 of the loss of duties, and 17 of the hospitalizations.

And then this row is the events that the committee based on the VAERS form and the medical records that they were able to obtain came to the conclusion on whether they were certainly or probably

caused by the vaccine, 50 out of 72, 5 out of 17. This of course includes possibles, unlikelies, unclassifiables, so it's a bit of a mix. The 50 involve, mostly address the site reactions, but some other ones as well. There's hypersensitivity pneumonitis case among there. The hospitalization is five. The five were all inflammation reaction to the injection site. Of the balance, the 12 includes a Guillian Barre case, a bi-polar disorder case and a lupus case, a wide variety of kinds of events that happen to people. Whether or not the vaccine precipitated that event, you see the determination of the committee. Some of these of course are in an possible group, but that, if you're interested, I could provide more data.

Yes, sir?

AUDIENCE MEMBER: You mentioned the systemic and the severe local reaction rates of about one percent.

LIEUTENANT COLONEL GRABENSTEIN: Right.

AUDIENCE MEMBER: If you gave a million doses there should be 10,000. How come you only have 314?

LIEUTENANT COLONEL GRABENSTEIN: The

clinicians rarely take the opportunity to report the events they see to the FDA. I mean it's a well known phenomenon with all drugs, not just vaccines. Serious events tend to be less under-reported than non serious events. There actually was a review article on the VAERS program in the Journal Vaccine about a month or two ago that reviews that in some detail.

DR. HAYWOOD: So there were no systemic --

LIEUTENANT COLONEL GRABENSTEIN: Well, no. Well, okay, the five here are injection site reactions. The hypersensitivity in the pneumonitis case is a systemic reaction and it is reflected in this group. But I've chosen not to define it by where it happened by organ system, but by impairment. That's how this data is arrayed. If you would like the data in some other array, I'd be happy to provide it to you that way. I've tried to present it in a way that I think is most practical or understandable. Please, if you would prefer me to report it in a different way at a future meeting, I'd be happy to do so.

One of the questions often asked of us

is, is this vaccine one of the causes of Gulf War illness? This line is a summary of the analysis, evaluations, decisions, conclusions that would say that it is not. And basically they all use pretty much the same language. There is no evidence of a link. And these three studies for the New England Journal regarding that corroborate essentially the same conclusion.

The educational efforts that we have to inform soldiers, sailors, airmen, Marines and Coast Guard of the value of vaccination are presented here. We have a trifold information sheet that is one of the key pieces. We have the draft almost finished of a quadfold that will provide more extensive information, and we anticipate collaborating with the CDC to turn it into a vaccine information statement similar to that available for influenza vaccine and most vaccines.

May of '99 was the first clinical conference at Ft. Detrick to bring providers and scientists together to talk about anthrax. We have the website that is kind of ground zero for information on the anthrax vaccination program. We have a toll free number and e-mail service to answer

people's questions, military, civilian, family member, civilian provider, what have you.

We have begun a series of site visits and open houses to go out and explain the facts to folks. You may have discussed this earlier today, we are about ready to release clinical practice guidelines that will provide some framework definition of cases and suggested management procedures for dealing with reactions of this size or that size, various types. And it has actually some value for many vaccines, especially inoculated vaccine beyond just anthrax.

We are working on, or I am intending to work on, let me put it that way, a comprehensive review document. You might think of it as a kind of ICIP statement. CDC is beginning to talk about releasing an ICIP statement on anthrax vaccine that would bring it together into one document, many of these items. And a training, video tape of a training CD ROM, also under development.

So anthrax vaccine, it's an inactivated vaccine. Safe and effective, the FDA says so, and everything we've accumulated would agreed with that. We've seen no unexpected reactions to date, and surveillance is ongoing. This last bullet is

probably a bit too conservative, a bit too optimistic. I think I would like to rephrase it to say there is no long term adverse event trends report. We've seen the odd case or two that represents the -- I mentioned. There's been a couple of Guillian Barres that have gone all the way up through the reporting system, one judged possibly related by the AVEC, one judged unlikely related by the AVEC largely based on the temporal sequence.

But we are actively engaged in assessing these reports and are trying to present them in the most open manner that we can. You know, although our confidence in the vaccine is strong, we are keeping an open mind and looking everywhere that we can to find the information we need.

We'll pause and see what comments you may have.

DR. PERROTTA: Any questions?

Dr. LaForce?

DR. LaFORCE: What's happened to refusals?

LIEUTENANT COLONEL GRABENSTEIN: Oh, thank you, I meant to mention that earlier. There is no central data collection regarding refusals. So

our best estimate is based on calling around and tracking down and that sort of thing. The number of refusals seems to have plateaued at about slightly more than 200 for the people offered vaccine to date or required to take vaccine to date, so it's something along there.

AUDIENCE MEMBER: Is refusal not one of the codes?

LIEUTENANT COLONEL GRABENSTEIN: Refusal is one of the codes, but their compliance with the codes is incomplete.

DR. PERROTTA: Other questions?

Interesting. Talking about it last night several of us judged this program as one of the well thought out ones from the beginning, taking into consideration the lessons that we've learned and perhaps not learned from Persian Gulf War and from Agent Orange and other things, so I personally think you are to be commended on this, and I would like to hear more as we continue.

LIEUTENANT COLONEL GRABENSTEIN: I would like that. I mean very sincerely I'd be happy to have further conversations. If you would like more data, please let us know because we value your

independent judgement of what we're doing here, and if you need more data to reach those kinds of conclusions, please let us know.

DR. PERROTTA: Okay.

LIEUTENANT COLONEL GRABENSTEIN: We have another question.

AUDIENCE MEMBER: Assuming, getting back to the 10,000 potential serious reactions --

LIEUTENANT COLONEL GRABENSTEIN: Correct.

AUDIENCE MEMBER: -- and you only got 314, which is what three percent of that. Either this is an extremely safe vaccine or the surveillance system isn't picking up the serious reactions. Can you come up with a way of evaluating that?

LIEUTENANT COLONEL GRABENSTEIN: Surely we are --

MR. CRODEL: Let me make a comment because I'm not only the victim of most of the bad publicity here, I'm Harvey Crodel from the Air Force Surgeon General's Office. And at Dover Air Force Base where there is an intense interest in this vaccine, right now out of about 1,100 people vaccinated we have I think at the present time 45 VAERS reports. They're extremely sensitive there.

There is a great deal of concern about the safety of the vaccine, particularly ones that were severe. We just don't seem to see the great number of the adverse events being reported, even in an area where there is a great deal of scrutiny.

I got my fourth short yesterday, so everyone, about 40 percent of the people are going to get an injection site reaction. You're going to see that. We even went out and told everybody absolutely and positively if anybody has any concern about any vaccine reaction to report it through VAERS. And I was expecting this huge calls of VAERS come flowing through and we just simply didn't see that.

BOARD MEMBER: So what you're telling me is you think it's really a very, very safe vaccine?

I think that the adverse reactions are not as intense to make patients concerned or providers concerned about the response to the vaccine. Yes, people are having responses. There are some people who had some significant responses, but in general I think what we're seeing with the study in Korea, the study that's there even under intense surveillance, it's not any more than we would expect to see. And I don't think many of the

patients are inclined to submit a VAERS report even when we tell them they should.

DR. POLAND: Remember too that what you're seeing is the difference between an active surveillance system with VAERS and a passive reporting system. And those passive reporting systems are very passive.

AUDIENCE MEMBER: I understand, but I thought we didn't know the active surveillance system here, you didn't show us the data for the active surveillance.

LIEUTENANT COLONEL GRABENSTEIN: The active surveillance is what's going on in Ft. Detrick with the 1,700, which is a lot easier to follow up. And basically if they don't pursue their follow-up evaluations they lose their BL4 containment privileges somehow, mechanically, automatically. That gets, nice compliance. So that's the value with this data that we're looking for.

COLONEL BRADSHAW: The other factor I think to be considered, which we have discussed, is also the congressional testimony that was about adverse events is it actually referred to the study is that with the Defense Medical Surveillance System

we have active surveillance of all hospitalizations and ambulatory visits in our population. And when you couple that with the tracking system that we have for immunization tracking, which we're doing for all three services, with anthrax we can link that data. And so that's part of the prospective and retrospective studies, is looking at a more comprehensive way of picking up potential adverse events or outcomes with the study population.

But as Dr. Poland mentioned, the CDC and the FDA recognize for all vaccines, not just anthrax that the VAERS reporting system underreports because it is passive surveillance. So it's like our, you know, reportable events list for anything else, you know, what we collect is really not a rate of disease, you know, or a rate of events, it's more a sentinel kind of surveillance system. So it's just one of the components that we can look at, but it's a misnomer to say that this is an actual rate of events, it's really more a reporting rate. That's why the rate is higher at Dover, you know, where we've emphasized it, than it is in the rest of the Air Force.

And another factor we probably ought to

mention, which Colonel Engler would probably want me to add, is that a lot of people are afraid, you know, to come in because they're afraid of some administrative sort of repercussions. Which is why we in the Air Force and I know the AVEC Committee is trying to get the word out that we're encouraging people to report, you know, any adverse event that they deem might be related to the vaccine.

DR. POLAND: If I might just point out too, last week in the New England Journal there is a review article on anthrax.

COLONEL ENGLER: I just think one other point that should be made is that the knowledge of the delivery sites about VAERS, about exemptions is frequently lacking. And if there is no supervising physician or primary care physician, the threshold of understanding of anything about vaccine adverse reactions is pretty absent, so that that acts as a second screen.

We receive numerous calls, as I said this morning, of temporal relationships which should be reported but were interpreted as well it couldn't be a vaccine. And then the other thing is that illness frequently now in our out-patient focused facilities,

you can be pretty darn sick and not be admitted to the hospital, so that's also not a threshold for some of the problems that might be linked.

LIEUTENANT COLONEL GRABENSTEIN: Our motto is if it filters up to our office, report it. Because they've surely gone through several steps before they found our phone number.

DR. PERROTTA: Okay, thanks again. I appreciate it, Colonel.

For everyone, we start at 7:30, bright and early please.

(Whereupon, at 5:19 p.m., the meeting was adjourned to reconvene tomorrow morning at 7:30 a.m.)